EXHIBIT 11

ISSUE CLASSIFICATION | Class 604 | Subclass 263

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UTILITY SERIAL NUMBER 08/696898 | PATENT DATE OCT 19 1999 | PATENT NUMBER [redacted]

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
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APPLICANTS: HENNING M. EJLERSEN, VEDBAEK, DENMARK.

CONTINUING DATA********
VERIFIED THIS APPLN IS A 371 OF PCT/DK95/00085 02/27/95
OR RS

FOREIGN/PCT APPLICATIONS********
VERIFIED ~~FED REP GERMANY~~ DENMARK 0236/94 02/28/94
OR RS

Foreign priority claimed 35 USC 119 conditions met	Verified and Acknowledged	Examiner's initials	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
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ADDRESS:
STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

TITLE: NEEDLE UNIT MAGAZINE AND REMOVABLE

6/8/99

U.S. DEPT. of COMMERCE-Patent and Trademark Office-PCT-436L (rev. 7-94)

PARTS OF APPLICATION FILED SEPARATELY 2 2792 | Formal Drawings (5 sht(s)) set 1 | 8-9-99 | E. Colbert Applications Examiner

NOTICE OF ALLOWANCE MAILED	Assistant Examiner	CLAIMS ALLOWED: Total Claims	Print Claim
6/8/99		15	1

ISSUE FEE: Amount Due	Date Paid	DRAWING: Sheets Drwg.	Figs. Drwg.	Print Fig.
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Label Area

RONALD K. STRIGHT, JR
PRIMARY EXAMINER
3762 Primary Examiner

ISSUE BATCH NUMBER 1161

PREPARED FOR ISSUE

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Form PTO-436A (Rev. 8/92)

ISSUE FEE IN FILE

Formal Drawings (___ sht(s)) ___

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08/696898

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INITIALS SEP 06 9628

D295/00085

PATENT APPLICATION

08696898

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	2. PCT/DO/EO/903	8-22-96
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SEARCHED

Class	Sub.	Date	Exmr.
604	263, 192		
	232, 199		
	110, 111		
	194, 239		
	240-243		
	198, 181		
	187,		
128	919		
206	363-368		
	438, 514	9/26/97	RS
Updated	Search	7/7/98	RS
Updated Search		6/8/99	RS

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
604	263, 192		
	240, 199		
206	365		
		6/8/99	DS

SEARCH NOTES

	Date	Exmr.

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PATENT NUMBER

APPLICATION SERIAL NUMBER
08/696,898

APPLICANT'S NAME (PLEASE PRINT)
EJLERSEN

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INTERNATIONAL CLASSIFICATION

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ORIGINAL CLASSIFICATION

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CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)			
604	192	240	199	
206	365			

GROUP ART UNIT: 3762

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RONALD K. STRIGHT, JR.

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U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

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United States Patent [19]

Ejlersen

[11] Patent Number: 5,968,021

[45] Date of Patent: Oct. 19, 1999

[54] **MAGAZINE AND REMOVABLE NEEDLE UNIT**

[75] Inventor: **Henning Munk Ejlersen**, Vedbaek, Denmark

[73] Assignee: **Novo Nordisk A/S**, Bagsvaerd, Germany

[21] Appl. No.: **08/696,898**

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[86] PCT No.: **PCT/DK95/00085**

§ 371 Date: **Aug. 22, 1996**

§ 102(e) Date: **Aug. 22, 1996**

[87] PCT Pub. No.: **WO95/23005**

PCT Pub. Date: **Aug. 3, 1995**

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Feb. 28, 1994 [DK] Denmark 0236/94

[51] **Int. Cl.**[6] **A61M 5/00**; B65D 83/10

[52] **U.S. Cl.** **604/263**; 604/192; 604/240; 604/199; 206/365

[58] **Field of Search** 604/263, 192, 604/232, 199, 110, 111, 194, 239, 240–243, 198, 181, 187; 128/919; 206/363–368, 438, 514

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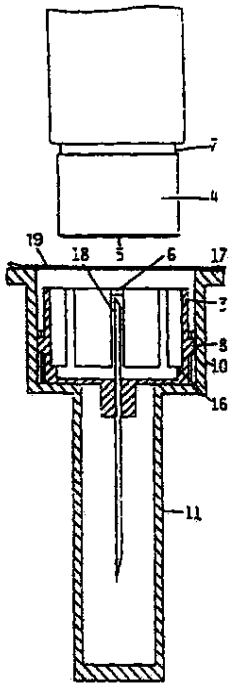
Primary Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Steve T. Zelson, Esq.

[57] **ABSTRACT**

A needle unit comprises a needle mounted in a hub having a sleeve made from a deformable material and surrounding an end of the needle at a radial distance from that needle. The sleeve is designed to be snap-locked onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging a circumferential recess in the outer wall of the connecting piece. It is also designed such that the locking engagement between the protrusions of this sleeve and the recess of the connecting piece is released when certain zones of the outer sleeve wall are pressed inwardly. A magazine for storing the needle unit comprises a compartment which can receive the needle unit in a plurality of rotational positions. The needle unit and magazine include a syringe/needle unit release mechanism which, in a first rotational position, does not press the release zones inwardly, thereby allowing the needle unit to lock onto the syringe, but which in a second rotational position, presses the release zones inwardly so that the needle disengages from the syringe and remains inside the magazine for disposal.

15 Claims, 5 Drawing Sheets



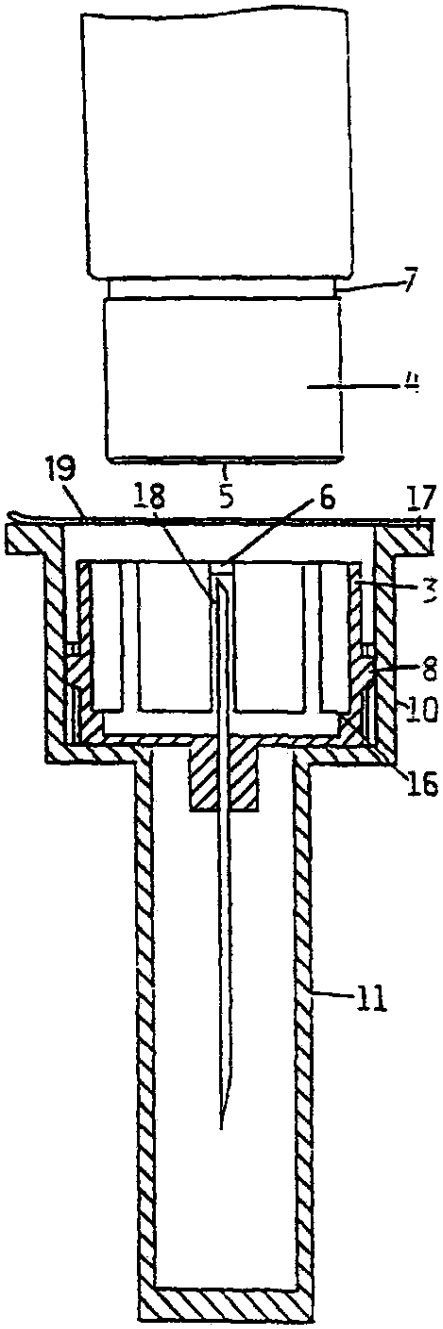


Fig. 1

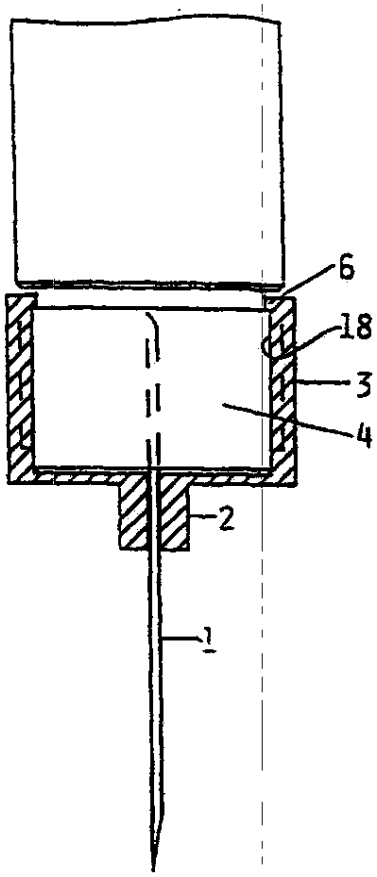


Fig. 2

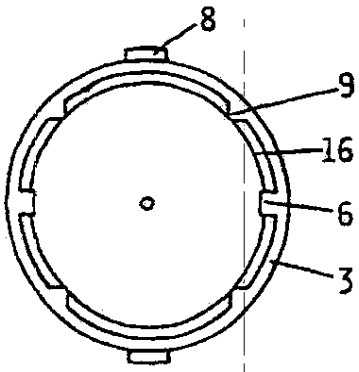
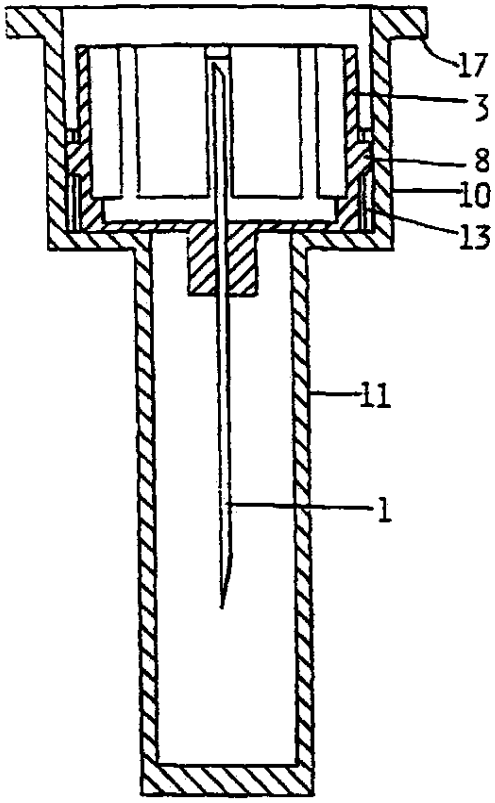


Fig. 3



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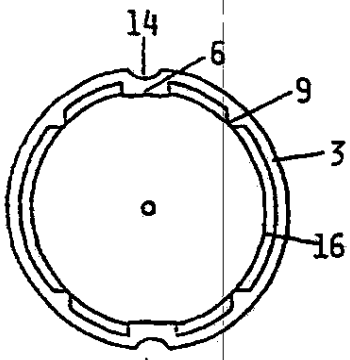

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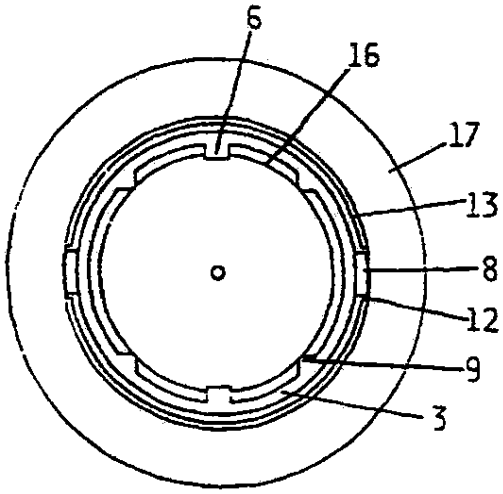

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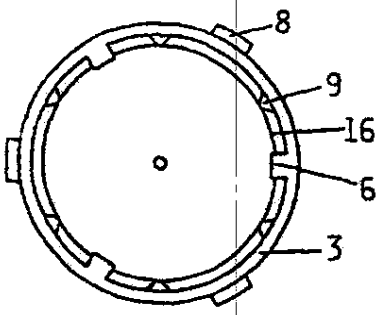
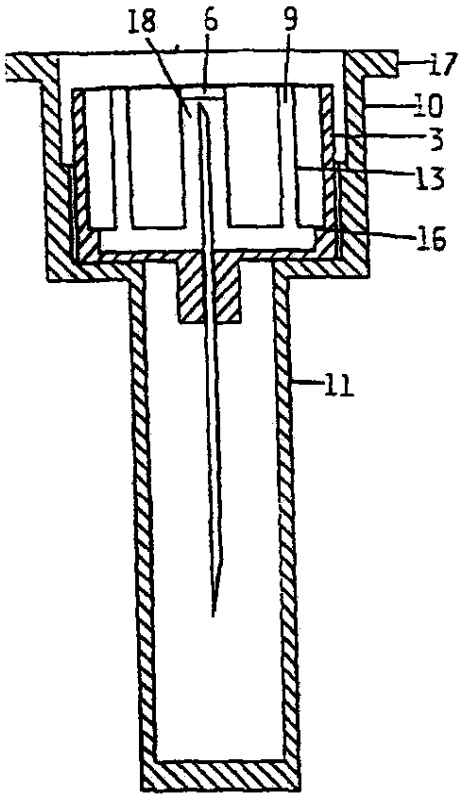


Fig. 9



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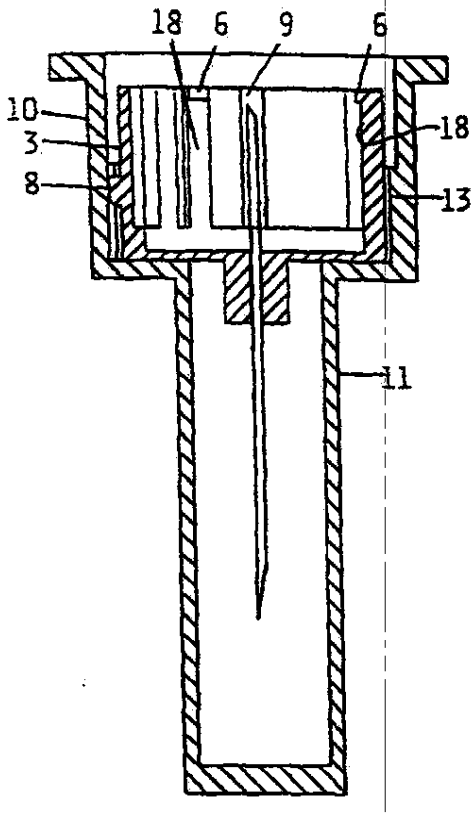
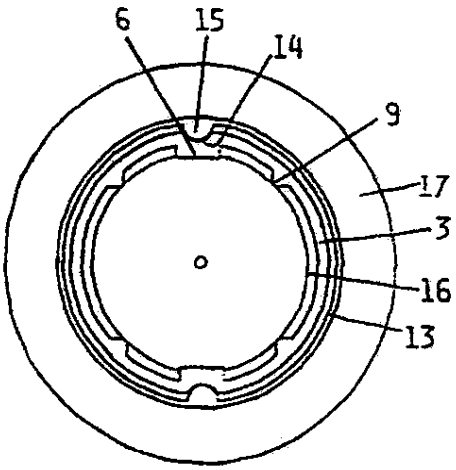


Fig. 10



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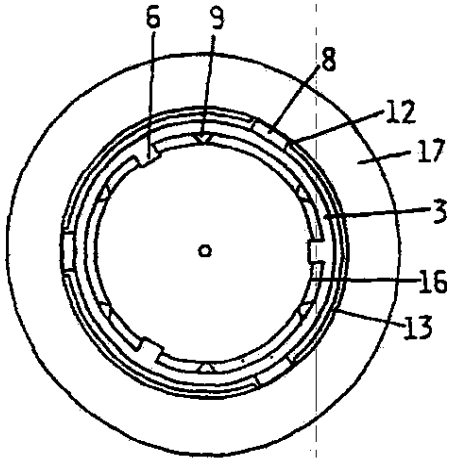

Fig. 11

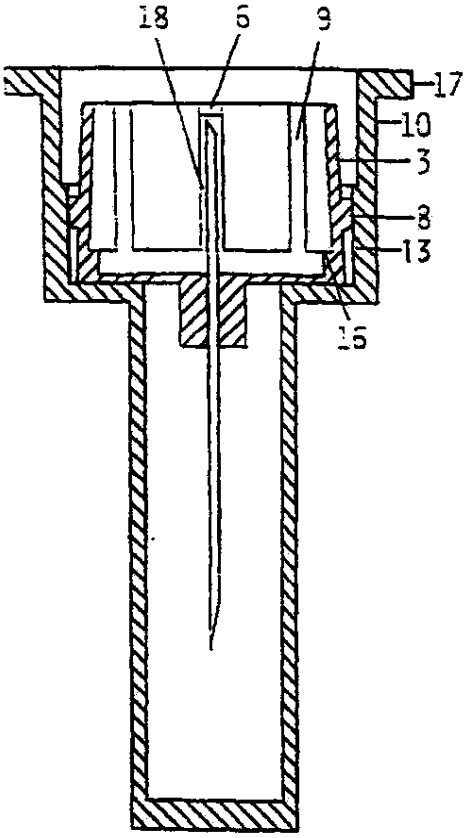

Fig. 12

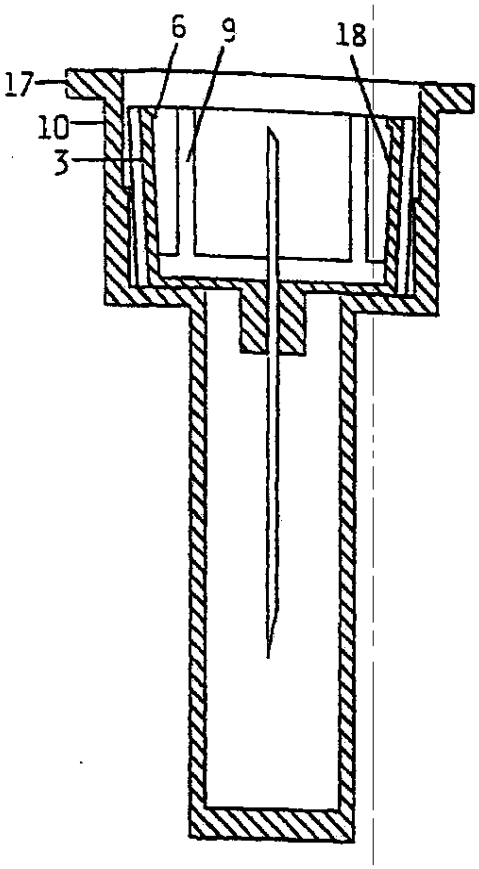

Fig. 14

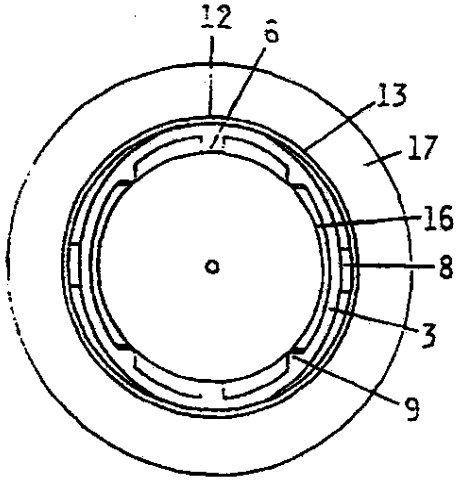

Fig. 13

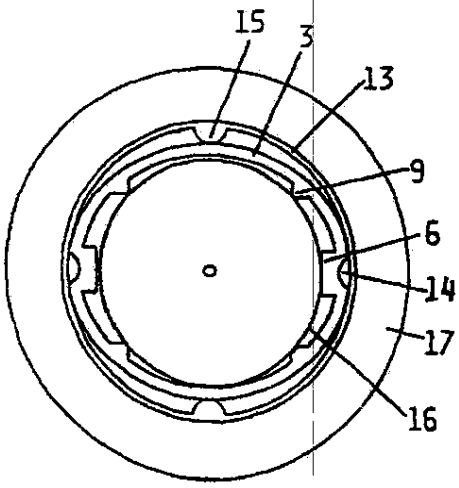

Fig. 15

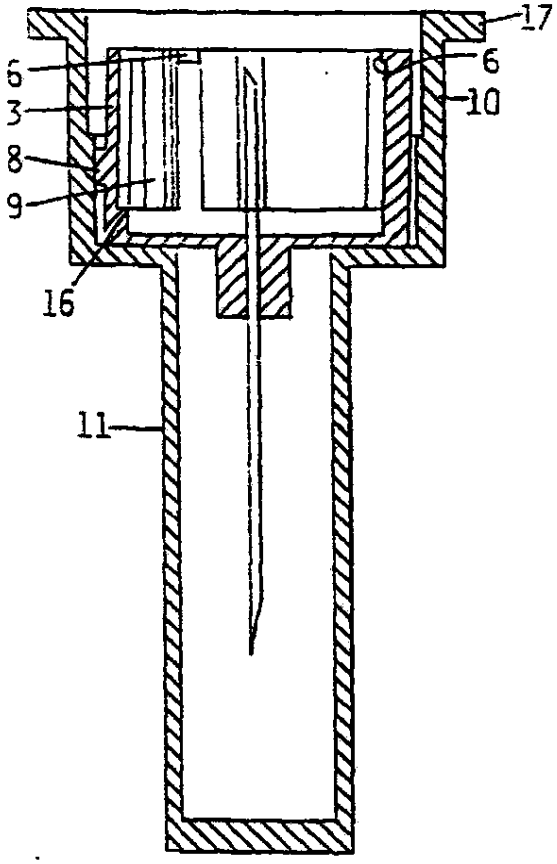

Fig. 16

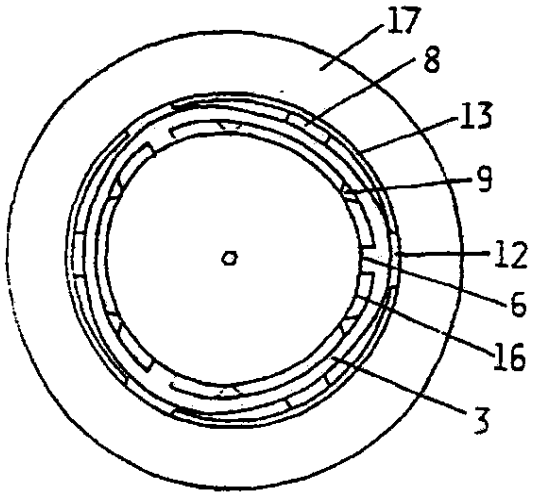

Fig. 17

MAGAZINE AND REMOVABLE NEEDLE UNIT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 35 U.S.C. 371 national application of PCT/DK95/00085 filed Feb. 27, 1995, which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

The invention relates to needle units for disposable injection needles, and specifically a needle unit comprising a needle mounted in a hub having a sleeve made from a plastic material and surrounding an end of the needle in a distance from that needle, the unit being designed to be mounted at the outlet end of a syringe having a cylindric connecting piece with a recess in a plane perpendicular to the cylinder axis, which connecting piece is received in the sleeve of the needle unit.

DESCRIPTION OF RELATED ART

By known needle units an inner surface of the depending sleeve is provided with an inner thread corresponding to an outer thread on the connecting piece of the syringe which the unit is intended for. The unit may then be mounted on the syringe simply by screwing it onto the connecting piece of the syringe.

However, such a screwing may be difficult to perform especially to people with reduced tactile motor function, and particularly unscrewing of a used unprotected sharp needle may be difficult if the screw connection has been carefully tightened when the unit was mounted.

Needle units are known of a type which can without screwing be mounted on a syringe which instead of a thread has a circumferential recess at the inner end of its connecting piece. Such needle units have at the inner side of their depending sleeves protrusions engaging the recess of the receiving connecting piece of the syringe. This construction is known from disposable syringes formed by snapping a needle unit onto the neck end of a cylinder ampoule, whereafter the syringe with the needle unit mounted is disposed of after use as a unity, as the needle unit cannot easily be demounted.

SUMMARY OF THE INVENTION

The object of the invention is to provide a needle unit of the snap-on type, which may easily be snapped onto a durable pen type syringe and which may easily be dismounted from the syringe to make it possible to change the needle without having to dispose of the syringe.

This is obtained by a needle unit of the above mentioned type, which unit is characterized in that the sleeve is so designed that the locking engagement between the protrusions of this sleeve and the recesses of the connecting piece is released when radial inward pressures are exerted on specific zones of the sleeve.

In an embodiment of the needle hub at least two protrusions may be provided on the inner surface of the sleeve, the apexes of these protrusions lying on a circle having its centre in the axis of the needle unit and having when the sleeve is not deformed a radius which is smaller than the radius of the connecting piece, and the connecting piece may fit into the sleeve with a play allowing deformation of the sleeve to an extent enlarging the radius of the circle through the apexes of the protrusions to be at least equal to the radius of the connecting piece.

The sleeve may either be deformed when the connecting piece is pressed into the sleeve urging the protrusions to pass over the side wall of this connecting piece until they snap into the recesses in this wall, or the deformation may be obtained by applying a radial inward pressures on the outer side of the sleeve at zones circumferentially displaced from the position of the protrusions. By such radial pressures the sleeve will be deformed so that the protrusions will be drawn out of the recesses in the connecting piece.

To prevent the sleeve from wriggling on the connecting piece due to the play between this sleeve and connecting piece, longitudinal spacer ribs may be provided on the inner surface of the sleeve at positions lying between the protrusions and zones lying halfway between the protrusions, which zones are designed for application of radial inward pressures.

Such spacer ribs are especially indispensable when according to the invention only two protrusions are provided diametrically opposite each other.

In another appropriate embodiment of the invention three protrusions are provided 120° circumferentially spaced. To dismount this needle unit an inward pressure may be exerted at three zones of the periphery of the sleeve, which zones must be circumferentially displaced relative to the points bearing the protrusions.

As the inward protrusions are not visible from the outer side of the sleeve, the positions of the zones for application of radial inward pressures may be indicated on the outer surface of the sleeve. The indication of the zones may appropriately be protrusions on the outer surface of the sleeve. These outward protrusions may serve further purposes as it will be described below.

The invention also concerns a magazine in which the needle unit may be stored. Such a magazine is characterized in that it comprises a compartment conforming the outer contour of the needle unit and having an access opening. The walls of this compartment may be strengthened against deformation and means for cooperation with the zones wherein radial inward pressures shall be exerted to release the hub may be provided.

The means for cooperating with the said zones may be the edge of the access opening of the magazine or of an inner strengthening of the compartment wall, which may be circular with outward recesses for accommodation of outward protrusions at the pressure zones of the sleeve when an unused needle unit is stored in the magazine, whereas engagement between the protrusions at the pressure zones of the needle unit and said edge will provide an inward pressure at said zones, when the unit is inserted in an empty magazine in a rotational position not bringing the outward protrusions on the sleeve into the outward recesses of the access opening or the strengthening of the magazine.

In another embodiment ribs may be provided on an inner cylindric wall of the compartment. In this case the sleeve must be provided with recesses in its outer cylindric wall, which recesses may accommodate said ribs when an unused needle unit is stored in the magazine. These recesses are provided in the outer wall at the positions wherein the inward protrusions of the needle hub sleeve are provided and thereby indirectly indicates the position of the pressure zones as the zones between two recesses. When a needle unit is returned to a magazine in a rotational position wherein the ribs are not accommodated in the recesses, the ribs will exert a pressure on the zones lying between these recesses and will provide the necessary deformation of the sleeve to release the engagement between the inward protrusions of the sleeve and the recesses of the connecting piece of the syringe.

The compartment wall is strengthened to be able to impart the necessary pressure to the zones without being deformed itself. This strengthening may be obtained by the access opening being surrounded by a flange. This flange and the compartment of the magazine may be one integral plastic member.

The flange may appropriately be used as the support for a foil which fixed to the flange covers the access opening and seals the compartment

BRIEF DESCRIPTION OF THE DRAWINGS

In the following a needle unit and a magazine according to the invention will be described in further details with references to the drawing, wherein

FIG. 1 shows a sectional view of a magazine with a needle unit according to the invention and a connecting piece for receiving the unit,

FIG. 2 shows schematically the needle unit in FIG. 1 rotated 90° and mounted on the connecting piece,

FIG. 3 shows the needle unit in FIGS. 1 and 2 seen from the open end of the sleeve,

FIG. 4 shows a sectional side view of the needle unit of FIGS. 1 to 3 stored in a magazine,

FIG. 5 shows the magazine with the stored needle unit of FIG. 4 seen from the access end of the magazine,

FIG. 6 shows another embodiment of a needle unit seen from the open end of the sleeve,

FIG. 7 shows a sectional side view of the needle unit of FIG. 6 stored in a magazine,

FIG. 8 shows the magazine of FIG. 7 with the stored unit seen from the open end of the magazine,

FIG. 9 shows still another embodiment of a needle unit seen from the open end of the sleeve,

FIG. 10 shows a sectional side view of the needle unit of FIG. 9 stored in a magazine,

FIG. 11 shows the magazine of FIG. 10 with the stored needle unit seen from the open end of the magazine,

FIG. 12 shows a sectional side view of a magazine with a needle unit according to FIGS. 1–3 finally deposited in the magazine,

FIG. 13 shows the magazine and needle unit of FIG. 12 seen from the access opening of the magazine,

FIG. 14 shows a sectional side view of a magazine with the needle unit of FIG. 6 finally deposited in this magazine,

FIG. 15 shows the magazine of FIG. 14 seen from its open access end,

FIG. 16 shows a sectional side view of a magazine with the needle unit of FIG. 9 finally deposited in this magazine, and

FIG. 17 shows the magazine of FIG. 16 seen from its open access end.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a needle unit stored in a magazine. The needle unit comprises a needle 1 mounted in a needle hub 2 which has a depending sleeve 3 surrounding an end of the needle 1 in some distance from this needle. The depending sleeve 3 is designed to be received on a cylindric connecting piece 4 of a syringe so that the surrounded part of the needle penetrates a not shown rubber membrane forming at least a part of an end surface 5 of the connecting piece 4.

At two diametrically opposite positions on the inner wall of the sleeve 3 inward protrusions 6 are provided. The protrusions 6 are designed to engage a circumferential recess 7 in the connecting piece 4 receiving the needle.

In FIG. 2 the needle unit has been rotated 90° and the receiving connecting piece 4 has been inserted into the needle unit, and it is shown how the protrusions 6 engage the recesses 7 of the connecting piece. The receiving connecting piece may be a closure part of a cylinder ampoule and the recess may be provided at the neck part of such an ampoule, but here the connecting piece is a part especially designed for cooperation with a needle unit according to the invention.

The needle hub is manufactured of a plastic material which allow some deformation of the sleeve 3 so that the diametrical distance between the apexes of the protrusions 6, which distance is smaller than the diameter of the connecting piece 4 when the sleeve is not deformed, may be increased to allow the inward protrusions 6 to pass over the side wall of the connecting piece 4 until they can snap into the recess 7 when the connecting piece 4 is pressed into the open end of the sleeve 3. During this insertion of the connecting piece 4 the open end of the sleeve 3 is deformed from having a circular appearance into an oval appearance, i.e. when the diameter connecting the inward protrusions is increased the diameter perpendicular thereto will be decreased. The not deformed sleeve must be designed to fit over the connecting piece with a play allowing this decrease.

To prevent the needle unit from wriggling due to the space between the outer wall of the connecting piece and the inner wall of the sleeve, a number of spacer ribs 9 are provide on the inner wall of the sleeve 3. These ribs will keep the connecting piece 4 centred in the sleeve 3.

In FIG. 3 the needle unit is seen from the open end of the sleeve. The radius of the connecting piece is indicated by a circle 16 which is formed by an edge of a guide at the inner end of the sleeve, into which guide the end of the connecting piece fits. Axial spacer ribs 9 are provided on the inner wall of the sleeve at both sides of the inward protrusions 6 but leaving the zones 90° displaced from the inward protrusions free to be pressed axially inwards until it contacts the wall of the connection piece. As indicated in FIG. 2, ribs 18 are also provided extending longitudinally in the sleeve from the inward protrusions to said guide at the inner end of the sleeve. During the exertion of the radial pressure at the said zones the spacer ribs 9 abut the connecting piece and act as fulcrums assisting the lifting of the inward protrusions 6 out of engagement with the recess 7 of the connecting piece.

When it is wanted to dismount the needle unit from the connecting piece, radial inward pressures may by two fingers be imparted on the outer side of the sleeve at said zones to disconnect the snap engagement between the inward protrusions 6 and the recess 7 of the connecting piece. Therefore it is necessary that marks on he outer side of the sleeve indicate the position of such zones or indicate the positions of the inward protrusions.

In the embodiment shown in the FIGS. 1–3 such marks are provided as outward protrusions 8 on the outer wall of the sleeve 3. These protrusions have another function which will be described below.

When a new and unused the needle unit is stored in a magazine as shown in FIGS. 4 and 5, the hub with its sleeve is supported in a compartment 10 into which it fits with a play allowing the necessary deformation of the sleeve 3. The inner space of the compartment conforms the outer contour of the hub 2, i.e. longitudinal recesses are provided in the inner wall of the compartment to accommodate the outward protrusions 8 on the sleeve 3. The needle is protected by a needle cap 11 integral with the compartment 10.

To mount a new needle unit on a syringe, the user may grasp the magazine with the unit with one hand without any risk of scratching himself by the needle. With his other hand he may grasp the syringe and insert the connecting piece of this syringe into the open end of the sleeve, the open end of which faces an open access end of the compartment of the magazine. The connection piece 4 is now pressed into the sleeve until the inward protrusions 6 of this sleeve snap into the recess 7 of this connection piece. The needle unit may now be drawn out of the magazine by the syringe.

When a used needle unit shall be disposed of, this needle unit mounted on the syringe is reinserted in the magazine but in a rotational position wherein the outward protrusions 8 of the sleeve 3 are not accommodated in the recesses 12. Thereby the outward protrusions 8 will abut a reinforcement 13 in the compartment and will be pressed radially inwards. As the outward protrusions of the sleeve are provided at the zones at which a radially inward pressure will deform the sleeve in a way bringing the inward protrusions of this sleeve out of engagement with the recesses of the connection piece, the needle unit will be disconnected from the syringe. As the outward protrusions of the sleeve are pressed into the reinforced part of the compartment, the unit will be wedged in this part and will not follow the syringe when it is retracted. A remounting of the needle unit is not possible as the sleeve remains in a deformed condition so that the inward protrusion of the sleeve will not engage the recesses of the connecting part if this part is reinserted in the sleeve. FIGS. 12 and 13 shows the described needle unit wedged into the magazine for final deposition.

To ensure that the sleeve 3 and not the compartment 10 is deformed, when the used needle unit is wedged into this compartment, the compartment wall is reinforced by the provision of the part 13 having an enlarged wall thickness. As another reinforcing feature helping the compartment 10 to keep its cylindric shape, a flange 17 is provided surrounding the access opening of the compartment. The flange 17 may further act as a support for a closure. This closure may be a foil 19 sealed along the flange 17 to enable a sterile storage of the unused needle unit.

FIG. 6 shows another embodiment of a needle unit seen from the open end of the sleeve. This embodiment differs from the one shown in FIG. 6 by the positions of the inward protrusions 6 being indicated by longitudinal grooves 14 in the outer surface of the sleeve 3. FIGS. 7 and 8 shows this unit stored in a magazine having a compartment 10, a needle cap 11, and a flange 17 as has the magazine of FIGS. 4 and 5. The recesses 12 of the magazine of FIGS. 4 and 5 are in FIGS. 7 and 8 replaced by longitudinal ribs 15 which are accommodated in the grooves 14 of the needle unit when this needle unit is new and stored in the magazine. When a used needle unit is reinserted in the magazine it shall be rotated with its grooves 14 displaced 90° from the ribs 15 of the compartment. The ribs 15 will then exert the radial inward pressures on the sleeve 3 which are necessary to disengage the inward protrusions 6 of this sleeve from the recess 7 of the connecting piece. FIGS. 14 and 15 shows a needle unit of the kind just described wedged into its magazine for final deposition.

It shall be noticed that by embodiments wherein the inward pressures are provided by ribs in the compartment, the used needle unit must be reinserted into the compartment in a rotational position by which it is ensured that the ribs acts at the zones designed for being the objects of radially inward pressures. In embodiments using outward protrusions on the sleeve of the needle unit it is inherently ensured that pressures exerted by the protrusions abutting elements in the compartment are exerted at the zones carrying the outward protrusions. The only demand as to the rotational position when reinserted is that this position must differ from the position of the original storage with the outward protrusions accommodated in recesses.

Elements of the FIGS. 6, 7, and 8 which corresponds to the elements of the embodiment described in FIGS. 1–5 are given the same reference numerals.

FIGS. 9, 10, and 11 shows still another embodiment for a needle unit and the magazine for its storage and final deposition wherein three inward protrusions 6 are provided on the sleeve 3 at 120° intervals along the inner periphery thereof. Outward protrusions 8 are provided at the zones where radially inward pressures must be exerted to release the snap engagement between the needle unit and a syringe. Spacer ribs 9 are provided in pairs at both sides of each inward protrusion leaving zones for exertion of radially inward pressures to deform the sleeve. The compartment of the magazine for storage of the new needle unit has three recesses for accommodating the outward protrusions 8 of the needle unit.

In FIGS. 16 and 17 it is shown how a used needle unit of this kind is wedged into the magazine for final deposition.

It appears that the needle unit will always be either mounted on a syringe or stored or disposed of in a magazine.

I claim:

1. In combination a magazine and a removable needle unit,

wherein said needle unit comprises a needle mounted in a hub and a sleeve made from a deformable material surrounding an end of the needle at a distance from said needle, said sleeve including at least one snap-lock element designed to engage a cooperating element on the outlet end of a syringe for securing said needle unit on the syringe, and wherein said sleeve includes specific zones, spaced from said at least one snap-lock member, which when pressed radially inwardly deform said sleeve in a manner such that the locking engagement between said sleeve and the syringe outlet end is released; and

wherein said magazine comprises a compartment for accommodating said needle unit in a plurality of rotational positions; and wherein said needle unit and magazine further include a syringe/needle unit release means which does not press said zones radially inwardly in a first rotational position of said needle unit, such that the needle unit may lock onto a syringe outlet end, and which presses said zones radially inwardly in a second rotational position of said needle unit, thereby causing said needle unit to release from a syringe outlet end.

2. A magazine and needle unit according to claim 1, wherein said syringe/needle unit release means comprises protrusions provided on the needle hub at said zones and a reinforcement part in said magazine which engages said protrusions in said second rotational position to press said zones inwardly, and which includes recesses to receive said protrusions in said first rotational position so as not to press said zones inwardly.

3. A magazine and needle unit according to claim 2, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

4. A magazine and needle unit according to claim 3, wherein said flange and said compartment are one integral plastic member.

5. A magazine and needle unit according to claim 4, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

6. A magazine and needle unit according to claim 3, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

7. A magazine and needle unit according to claim 1, wherein said syringe/needle unit release means comprises a plurality of axial ribs on an inner wall of said magazine which press said specific zones inwardly in said second rotational position, and wherein said sleeve includes a plurality of axial recesses for receiving said ribs in said first rotational position so as not to press said zones inwardly.

8. A magazine and needle unit according to claim 7, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

9. A magazine and needle unit according to claim 8, wherein said flange and said compartment are one integral plastic member.

10. A magazine and needle unit according to claim 9, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

11. A magazine and needle unit according to claim 8, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

12. A magazine and needle unit according to claim 1, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

13. A magazine and needle unit according to claim 12, wherein said flange and said compartment are one integral plastic member.

14. A magazine and needle unit according to claim 13, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

15. A magazine and needle unit according to claim 12, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

* * * * *

08/686898

PATENT APPLICATION SERIAL NO.

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

PTO-1556
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19113 09/03/96 08869898 14-1447 190 960 1.010.00CH

ABSTRACT

A needle unit comprises a needle mounted in a hub having a sleeve made from a deformable material and surrounding an end of the needle at a radial distance from that needle. The sleeve is designed to be snap-locked onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging a circumferential recess in the outer wall of the connecting piece. It is also designed such that the locking engagement between the protrusions of this sleeve and the recess of the connecting piece is released when certain zones of the outer sleeve wall are pressed inwardly. A magazine for storing the needle unit comprises a compartment which can receive the needle unit in a plurality of rotational positions. The needle unit and magazine include a syringe/needle unit release mechanism which, in a first rotational position, does not press the release zones inwardly, thereby allowing the needle unit to lock onto the syringe, but which in a second rotational position, presses the release zones inwardly so that the needle disengages from the syringe and remains inside the magazine for disposal.

22 AUG 1996

WO 95/23005 PCT/DK95/00085

MAGAZINE AND REMOVABLE NEEDLE UNIT

Background OF The Invention

The invention relates to needle units for disposable injection needles, and specifically a needle unit comprising a needle mounted in a hub having a sleeve made from a plastic material and surrounding an end of the needle in a distance from that needle, the unit being designed to be mounted at the outlet end of a syringe having a cylindric connecting piece with a recess in a plane perpendicular to the cylinder axis, which connecting piece is received in the sleeve of the needle unit.

Description of Related Art

By known needle units an inner surface of the depending sleeve is provided with an inner thread corresponding to an outer thread on the connecting piece of the syringe which the unit is intended for. The unit may then be mounted on the syringe simply by screwing it onto the connecting piece of the syringe.

However, such a screwing may be difficult to perform especially to people with reduced tactile motor function, and particularly unscrewing of a used unprotected sharp needle may be difficult if the screw connection has been carefully tightened when the unit was mounted.

Needle units are known of a type which can without screwing be mounted on a syringe which instead of a thread has a circumferential recess at the inner end of its connecting piece. Such needle units have at the inner side of their depending sleeves protrusions engaging the recess of the receiving connecting piece of the syringe. This construction is known from disposable syringes formed by snapping a needle unit onto the neck end of a cylinder ampoule, whereafter the syringe with the needle unit mounted is disposed of after use as a unity, as the needle unit cannot easily be demounted.

Summary of The Invention

The object of the invention is to provide a needle unit of the snap-on type, which may easily be snapped onto a durable pen type syringe and which may easily be

dismounted from the syringe to make it possible to change the needle without having to dispose of the syringe.

This is obtained by a needle unit of the above mentioned type, which unit is characterized in that the sleeve is so designed that the locking engagement between the protrusions of this sleeve and the recesses of the connecting piece is released when radial inward pressures are exerted on specific zones of the sleeve.

In an embodiment of the needle hub at least two protrusions may be provided on the inner surface of the sleeve, the apexes of these protrusions lying on a circle having its centre in the axis of the needle unit and having when the sleeve is not deformed a radius which is smaller than the radius of the connecting piece, and the connecting piece may fit into the sleeve with a play allowing deformation of the sleeve to an extent enlarging the radius of the circle through the apexes of the protrusions to be at least equal to the radius of the connecting piece.

The sleeve may either be deformed when the connecting piece is pressed into the sleeve urging the protrusions to pass over the side wall of this connecting piece until they snap into the recesses in this wall, or the deformation may be obtained by applying a radial inward pressures on the outer side of the sleeve at zones circumferentially displaced from the position of the protrusions. By such radial pressures the sleeve will be deformed so that the protrusions will be drawn out of the recesses in the connecting piece.

To prevent the sleeve from wriggling on the connecting piece due to the play between this sleeve and connecting piece, longitudinal spacer ribs may be provided on the inner surface of the sleeve at positions lying between the protrusions and zones lying halfway between the protrusions, which zones are designed for application of radial inward pressures.

Such spacer ribs are especially indispensable when according to the invention only two protrusions are provided diametrically opposite each other.

In another appropriate embodiment of the invention three protrusions are provided 120° circumferentially spaced. To dismount this needle unit an inward pressure may be exerted at three zones of the periphery of the sleeve, which zones must be circumferentially displaced relative to the points bearing the protrusions.

As the inward protrusions are not visible from the outer side of the sleeve, the positions of the zones for application of radial inward pressures may be indicated on the outer surface of the sleeve. The indication of the zones may appropriately be protrusions on the outer surface of the sleeve. These outward protrusions may serve further purposes as it will be described below.

The invention also concerns a magazine in which the needle unit may be stored. Such a magazine is characterized in that it comprises a compartment conforming the outer contour of the needle unit and having an access opening. The walls of this compartment may be strengthened against deformation and means for cooperation with the zones wherein radial inward pressures shall be exerted to release the hub may be provided.

The means for cooperating with the said zones may be the edge of the access opening of the magazine or of an inner strengthening of the compartment wall, which may be circular with outward recesses for accommodation of outward protrusions at the pressure zones of the sleeve when an unused needle unit is stored in the magazine, whereas engagement between the protrusions at the pressure zones of the needle unit and said edge will provide an inward pressure at said zones, when the unit is inserted in an empty magazine in a rotational position not bringing the outward protrusions on the sleeve into the outward recesses of the access opening or the strengthening of the magazine.

In another embodiment ribs may be provided on an inner cylindric wall of the compartment. In this case the sleeve must be provided with recesses in its outer cylindric wall, which recesses may accommodate said ribs when an unused needle unit is stored in the magazine. These recesses are provided in the outer wall at the positions wherein the inward protrusions of the needle hub sleeve are provided and thereby indirectly indicates the position of the pressure zones as the zones between two recesses. When a needle unit is returned to a magazine in a rotational position wherein the ribs are not accommodated in the recesses, the ribs will exert a pressure on the zones lying between these recesses and will provide the necessary deformation of the sleeve to release the engagement between the inward protrusions of the sleeve and the recesses of the connecting piece of the syringe.

The compartment wall is strengthened to be able to impart the necessary pressure to the zones without being deformed itself. This strengthening may be obtained by the access opening being surrounded by a flange. This flange and the compartment of the magazine may be one integral plastic member.

The flange may appropriately be used as the support for a foil which fixed to the flange covers the access opening and seals the compartment

B

Brief Description of The Drawings

In the following a needle unit and a magazine according to the invention will be described in further details with references to the drawing, wherein

figure 1 shows a sectional view of a magazine with a needle unit according to the invention and a connecting piece for receiving the unit,

figure 2 shows schematically the needle unit in figure 1 rotated 90° and mounted on the connecting piece,

figure 3 shows the needle unit in figure 1 and 2 seen from the open end of the sleeve,

figure 4 shows a sectional side view of the needle unit of figure 1 to 3 stored in a magazine,

figure 5 shows the magazine with the stored needle unit of figure 4 seen from the access end of the magazine,

figure 6 shows another embodiment of a needle unit seen from the open end of the sleeve,

figure 7 shows a sectional side view of the needle unit of figure 6 stored in a magazine,

figure 8 shows the magazine of figure 7 with the stored unit seen from the open end of the magazine,

figure 9 shows still another embodiment of a needle unit seen from the open end of the sleeve,

figure 10 shows a sectional side view of the needle unit of figure 9 stored in a magazine,

figure 11 shows the magazine of figure 10 with the stored needle unit seen from the open end of the magazine,

figure 12 shows a sectional side view of a magazine with a needle unit according to figures 1 - 3 finally deposited in the magazine,

figure 13 shows the magazine and needle unit of figure 12 seen from the access opening of the magazine,

figure 14 shows a sectional side view of a magazine with the needle unit of figure 6 finally deposited in this magazine,

figure 15 shows the magazine of figure 14 seen from its open access end,

figure 16 shows a sectional side view of a magazine with the needle unit of figure 9 finally deposited in this magazine, and

figure 17 shows the magazine of figure 16 seen from its open access end.

B Description of the Preferred Embodiments

Figure 1 shows a needle unit stored in a magazine. The needle unit comprises a needle 1 mounted in a needle hub 2 which has a depending sleeve 3 surrounding

an end of the needle 1 in some distance from this needle. The depending sleeve 3 is designed to be received on a cylindric connecting piece 4 of a syringe so that the surrounded part of the needle penetrates a not shown rubber membrane forming at least a part of an end surface 5 of the connecting piece 4.

At two diametrically opposite positions on the inner wall of the sleeve 3 inward protrusions 6 are provided. The protrusions 6 are designed to engage a circumferential recess 7 in the connecting piece 4 receiving the needle.

In figure 2 the needle unit has been rotated 90° and the receiving connecting piece 4 has been inserted into the needle unit, and it is shown how the protrusions 6 engage the recesses 7 of the connecting piece. The receiving connecting piece may be a closure part of a cylinder ampoule and the recess may be provided at the neck part of such an ampoule, but here the connecting piece is a part especially designed for cooperation with a needle unit according to the invention.

The needle hub is manufactured of a plastic material which allow some deformation of the sleeve 3 so that the diametrical distance between the apexes of the protrusions 6, which distance is smaller than the diameter of the connecting piece 4 when the sleeve is not deformed, may be increased to allow the inward protrusions 6 to pass over the side wall of the connecting piece 4 until they can snap into the recess 7 when the connecting piece 4 is pressed into the open end of the sleeve 3. During this insertion of the connecting piece 4 the open end of the sleeve 3 is deformed from having a circular appearance into an oval appearance, i.e. when the diameter connecting the inward protrusions is increased the diameter perpendicular thereto will be decreased. The not deformed sleeve must be designed to fit over the connecting piece with a play allowing this decrease.

To prevent the needle unit from wriggling due to the space between the outer wall of the connecting piece and the inner wall of the sleeve, a number of spacer ribs 9

are provide on the inner wall of the sleeve 3. These ribs will keep the connecting piece 4 centred in the sleeve 3.

In figure 3 the needle unit is seen from the open end of the sleeve. The radius of the connecting piece is indicated by a circle 16 which is formed by an edge of a guide at the inner end of the sleeve, into which guide the end of the connecting piece fits. Axial spacer ribs 9 are provided on the inner wall of the sleeve at both sides of the inward protrusions 6 but leaving the zones 90° displaced from the inward protrusions free to be pressed axially inwards until it contacts the wall of the connection piece. As indicated in figure 2, ribs 18 are also provided extending longitudinally in the sleeve from the inward protrusions to said guide at the inner end of the sleeve. During the exertion of the radial pressure at the said zones the spacer ribs 9 abut the connecting piece and act as fulcrums assisting the lifting of the inward protrusions 6 out of engagement with the recess 7 of the connecting piece.

When it is wanted to dismount the needle unit from the connecting piece, radial inward pressures may by two fingers be imparted on the outer side of the sleeve at said zones to disconnect the snap engagement between the inward protrusions 6 and the recess 7 of the connecting piece. Therefore it is necessary that marks on the outer side of the sleeve indicate the position of such zones or indicate the positions of the inward protrusions.

In the embodiment shown in the figures 1 - 3 such marks are provided as outward protrusions 8 on the outer wall of the sleeve 3. These protrusions have another function which will be described below.

When a new and unused the needle unit is stored in a magazine as shown in figure 4 and 5, the hub with its sleeve is supported in a compartment 10 into which it fits with a play allowing the necessary deformation of the sleeve 3. The inner space of the compartment conforms the outer contour of the hub 2, i. e. longitudinal recesses

are provided in the inner wall of the compartment to accommodate the outward protrusions 8 on the sleeve 3. The needle is protected by a needle cap 11 integral with the compartment 10.

To mount a new needle unit on a syringe, the user may grasp the magazine with the unit with one hand without any risk of scratching himself by the needle. With his other hand he may grasp the syringe and insert the connecting piece of this syringe into the open end of the sleeve, the open end of which faces an open access end of the compartment of the magazine. The connection piece 4 is now pressed into the sleeve until the inward protrusions 6 of this sleeve snap into the recess 7 of this connection piece. The needle unit may now be drawn out of the magazine by the syringe.

When a used needle unit shall be disposed of, this needle unit mounted on the syringe is reinserted in the magazine but in a rotational position wherein the outward protrusions 8 of the sleeve 3 are not accommodated in the recesses 12. Thereby the outward protrusions 8 will abut a reinforcement 13 in the compartment and will be pressed radially inwards. As the outward protrusions of the sleeve are provided at the zones at which a radially inward pressure will deform the sleeve in a way bringing the inward protrusions of this sleeve out of engagement with the recesses of the connection piece, the needle unit will be disconnected from the syringe. As the outward protrusions of the sleeve are pressed into the reinforced part of the compartment, the unit will be wedged in this part and will not follow the syringe when it is retracted. A remounting of the needle unit is not possible as the sleeve remains in a deformed condition so that the inward protrusion of the sleeve will not engage the recesses of the connecting part if this part is reinserted in the sleeve. Figure 12 and 13 shows the described needle unit wedged into the magazine for final deposition.

To ensure that the sleeve 3 and not the compartment 10 is deformed, when the used needle unit is wedged into this compartment, the compartment wall is reinforced by the provision of the part 13 having an enlarged wall thickness. As another reinforcing feature helping the compartment 10 to keep its cylindric shape, a flange 17 is provided surrounding the access opening of the compartment. The flange 17 may further act as a support for a closure. This closure may be a foil ~~(not shown)~~ sealed along the flange 17 to enable a sterile storage of the unused needle unit.

Figure 6 shows another embodiment of a needle unit seen from the open end of the sleeve. This embodiment differs from the one shown in figure 6 by the positions of the inward protrusions 6 being indicated by longitudinal grooves 14 in the outer surface of the sleeve 3. Figure 7 and 8 shows this unit stored in a magazine having a compartment 10, a needle cap 11, and a flange 17 as has the magazine of figure 4 and 5. The recesses 12 of the magazine of figure 4 and 5 are in figure 7 and 8 replaced by longitudinal ribs 15 which are accommodated in the grooves 14 of the needle unit when this needle unit is new and stored in the magazine. When a used needle unit is reinserted in the magazine it shall be rotated with its grooves 14 displaced 90° from the ribs 15 of the compartment. The ribs 15 will then exert the radial inward pressures on the sleeve 3 which are necessary to disengage the inward protrusions 6 of this sleeve from the recess 7 of the connecting piece. Figure 14 and 15 shows a needle unit of the kind just described wedged into its magazine for final deposition.

It shall be noticed that by embodiments wherein the inward pressures are provided by ribs in the compartment, the used needle unit must be reinserted into the compartment in a rotational position by which it is ensured that the ribs acts at the zones designed for being the objects of radially inward pressures. In embodiments using outward protrusions on the sleeve of the needle unit it is inherently ensured that pressures exerted by the protrusions abutting elements in the compartment are

exerted at the zones carrying the outward protrusions. The only demand as to the rotational position when reinserted is that this position must differ from the position of the original storage with the outward protrusions accommodated in recesses.

Elements of the figures 6, 7, and 8 which corresponds to the elements of the embodiment described in figure 1 - 5 are given the same reference numerals.

Figure 9, 10, and 11 shows still another embodiment for a needle unit and the magazine for its storage and final deposition wherein three inward protrusions 6 are provided on the sleeve 3 at 120° intervals along the inner periphery thereof. Outward protrusions 8 are provided at the zones where radially inward pressures must be exerted to release the snap engagement between the needle unit and a syringe. Spacer ribs 9 are provided in pairs at both sides of each inward protrusion leaving zones for exertion of radially inward pressures to deform the sleeve. The compartment of the magazine for storage of the new needle unit has three recesses for accommodating the outward protrusions 8 of the needle unit.

In figure 16 and 17 it is shown how a used needle unit of this kind is wedged into the magazine for final deposition.

It appears that the needle unit will always be either mounted on a syringe or stored or disposed of in a magazine.

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07 -03- 1996

CLAIMS

1. A magazine for storing and final disposing of a needle unit of the kind comprising a needle mounted in a hub having a sleeve made from a flexible material and surrounding an end of the needle in a distance from that needle, this sleeve being designed to be snap-locked onto a connecting piece at the outlet end of a syringe and so designed that the locking engagement between this sleeve and the connecting piece is released when radial inward pressures are exerted on specific zones of the sleeve, characterized in that said magazine comprises a compartment conforming an outer contour of the needle unit to freely accommodate this needle unit in a number of rotational positions, and means cooperating with said specific zones to exert a radial pressure on the sleeve in these zones when the needle unit is inserted in the magazine in other rotational positions.

2. A magazine according to claim 1, characterized in that the compartment is strengthened by an access opening being surrounded by a flange.

3. A magazine according to claim 2, characterized in that the strengthening flange and the compartment is one integral plastic member.

4. A magazine according to claim 2 or 3, characterized in that the compartment is sealed by a foil fixed to the flange surrounding the access opening of the compartment.

AMENDED SHEET

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	Attorney's Docket Number: 3997.204-US

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Needle Unit

the specification of which (check only one item below):

[ ] is attached hereto

[ ] was filed as United States application

Serial No. _____

on _____,

and was amended

on _____(if applicable).

[X] was filed as PCT international application

Number PCT/DK95/00085

on 27 February, 1995,

and was amended under PCT Article 19

on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY	APPLICATION NUMBER	DATE OF FILING	PRIORITY CLAIMED
DK	0236/94	28 February 1994	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	Attorney's Docket Number: 3997.204-US

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)			
PCT/DK95/00085	27 February 1995			X	

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Steve T. Zelson, Esq. Reg. No. 30,335 Elias J. Lambiris, Esq. Reg. No. 33,728 Cheryl H. Agris Reg. No. 34,086 James J. Harrington, Esq. Reg. No. 38,711

Send Correspondence to: Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, New York 10017

Direct Telephone Calls To:
Steve T. Zelson
(212) 867-0123

1	Full Name of Inventor	Family Name: Ejlersen 1-00	First Given Name: Henning	Second Given Name: Munk
	Residence & Citizenship	City: Vedbaek	State or Foreign Country: Denmark DKX	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Bueager 31	City: Vedbaek	State & Zip Code/Country: Denmark
2	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Henning Ejlersen		
Date 4/7	Date	Date

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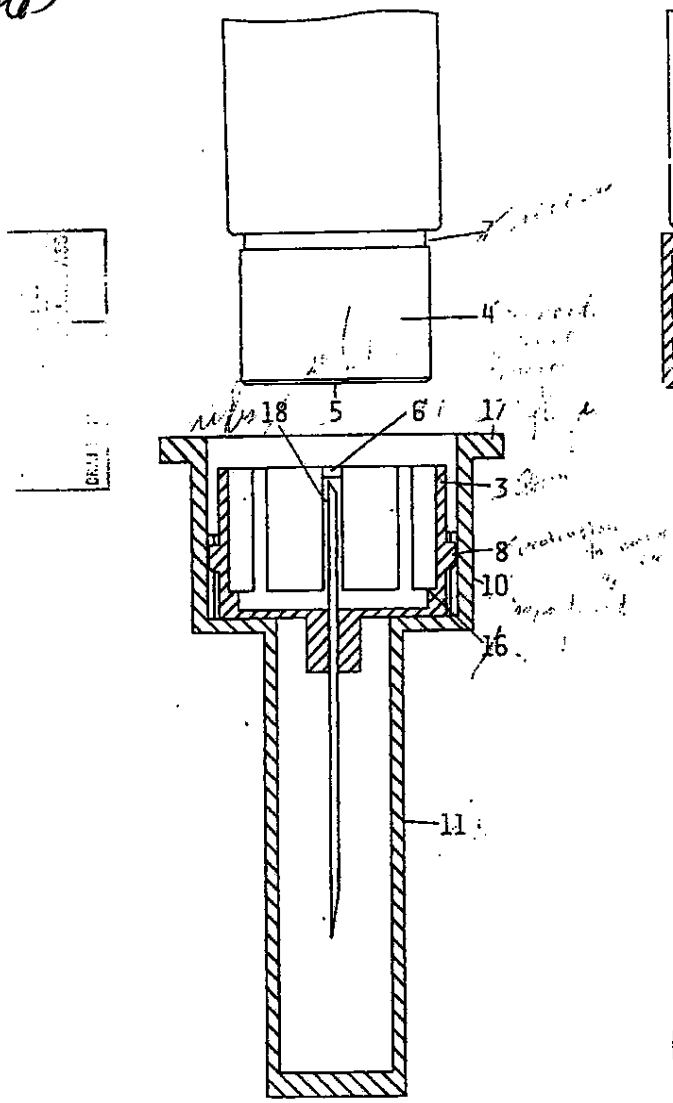

Fig. 1

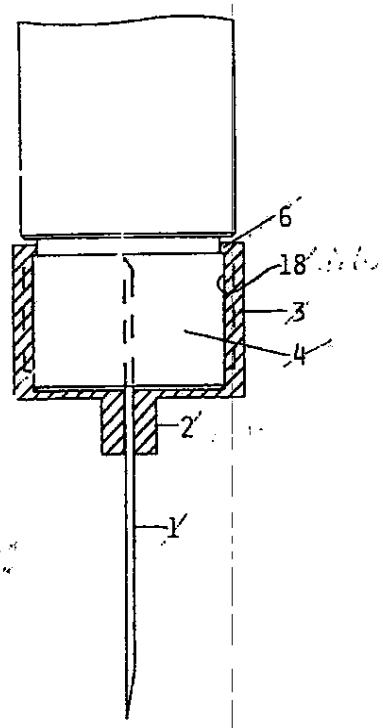

Fig. 2

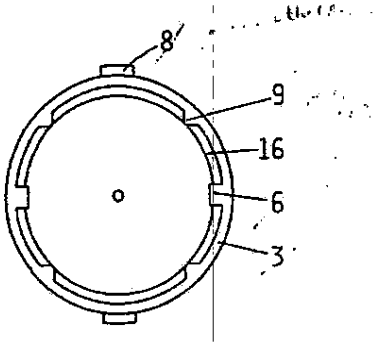

Fig. 3

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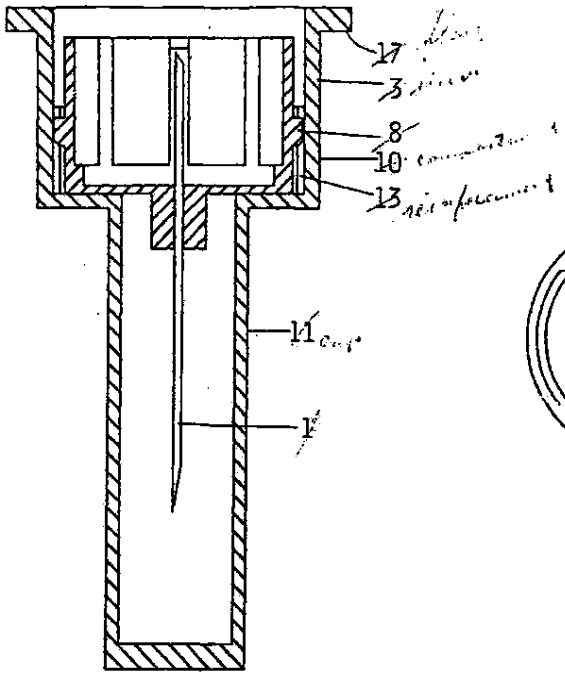

Fig. 4

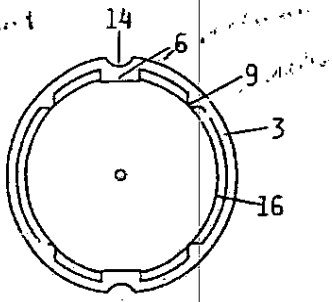

Fig. 6

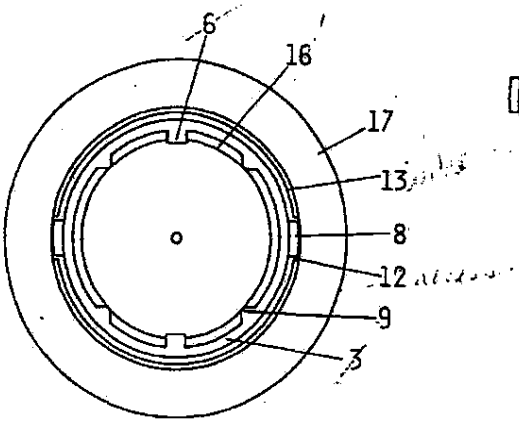

Fig. 5

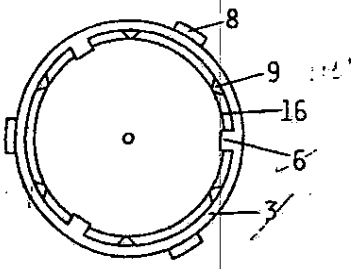

Fig. 9

PRINT OF DRAWINGS
AS ORIGINALLY FILED
WO 95/23005

PCT/DK95/00085

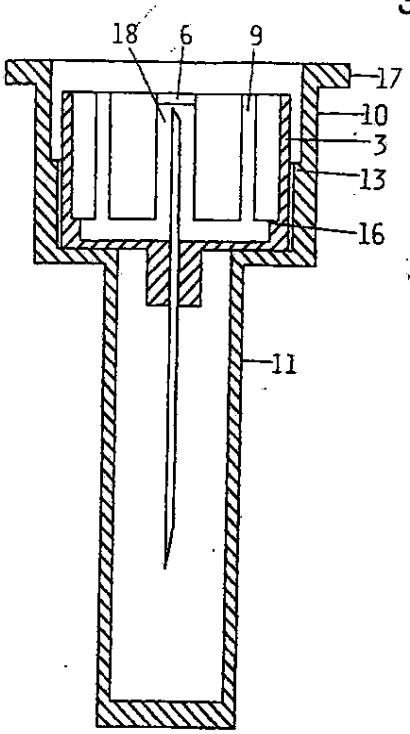

Fig. 7

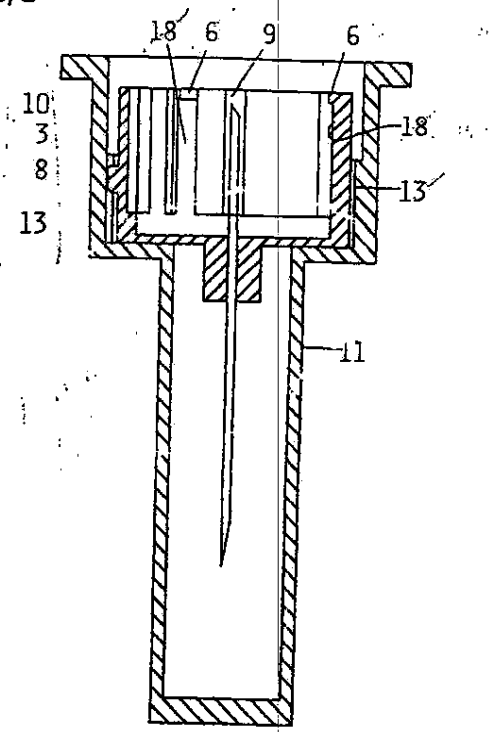

Fig. 10

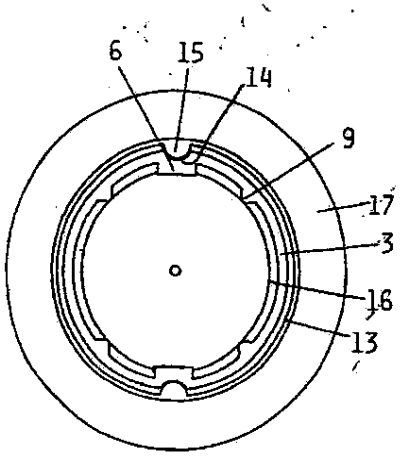

Fig. 8

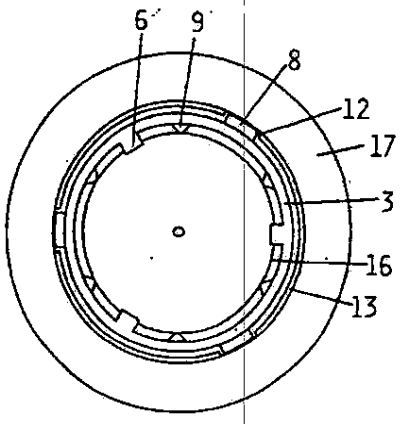

Fig. 11

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PCT/DK95/00085

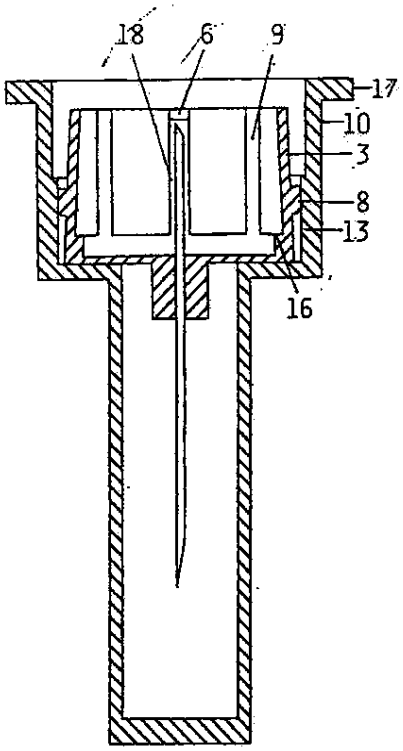
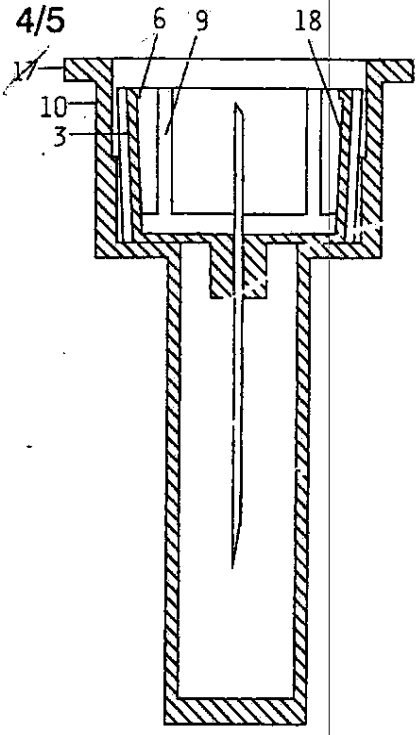


Fig. 12



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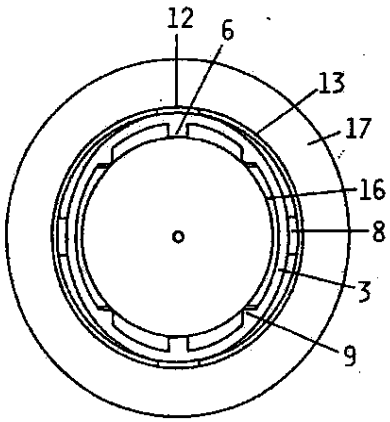

Fig. 13

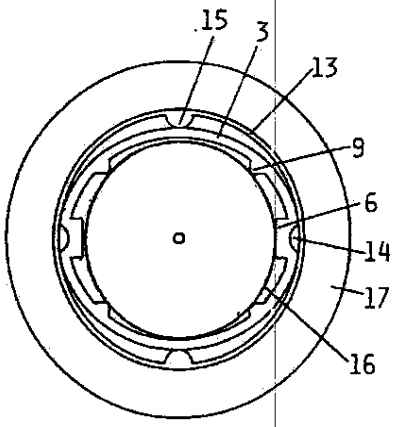

Fig. 15

PRINT OF DRAWINGS
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WO 95/23005

8/696898
PCT/DK95/00085

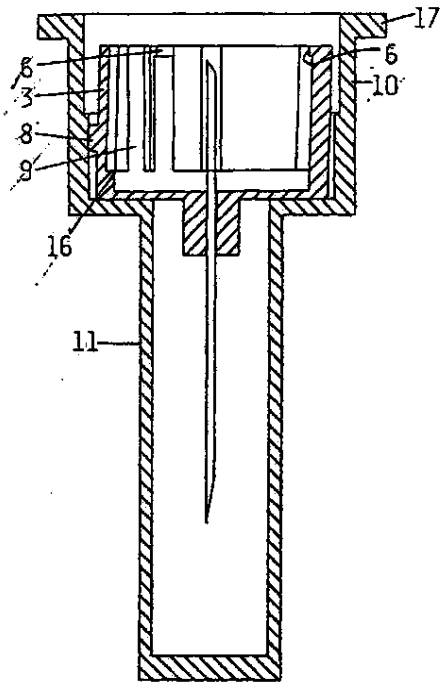


Fig. 16

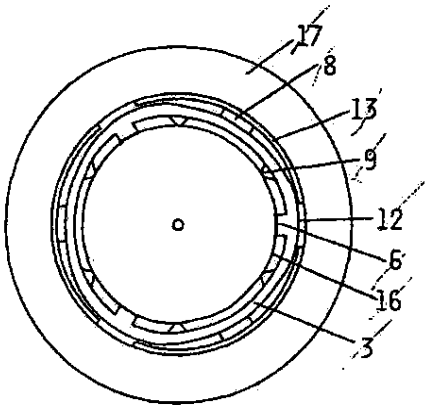


Fig. 17

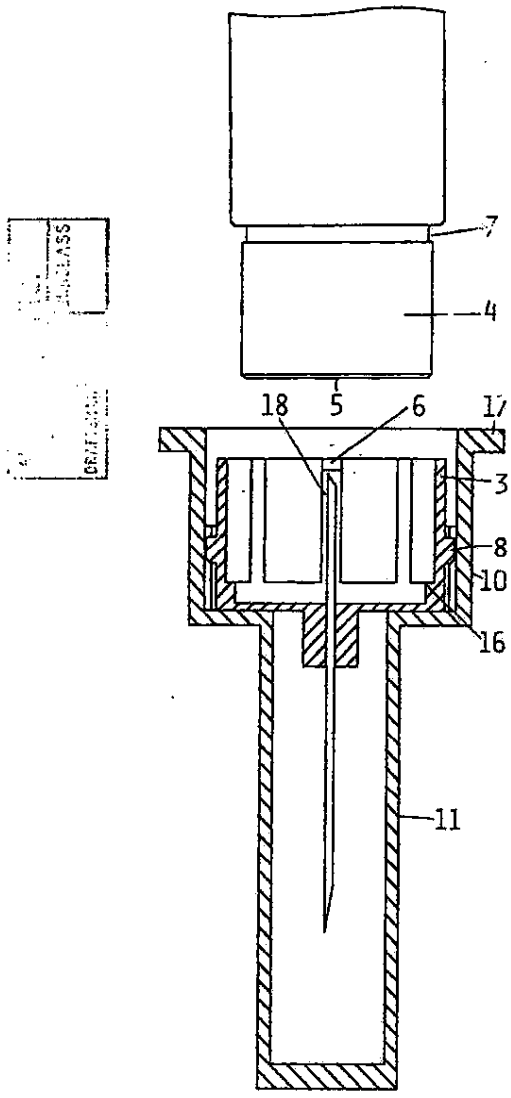


Fig. 1

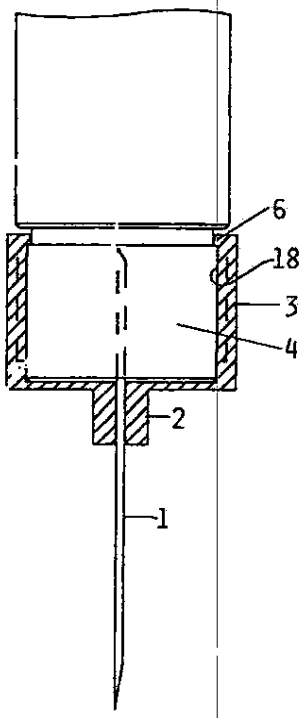


Fig. 2

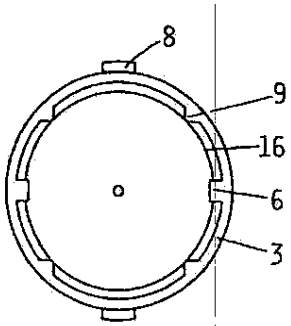


Fig. 3

8/696898

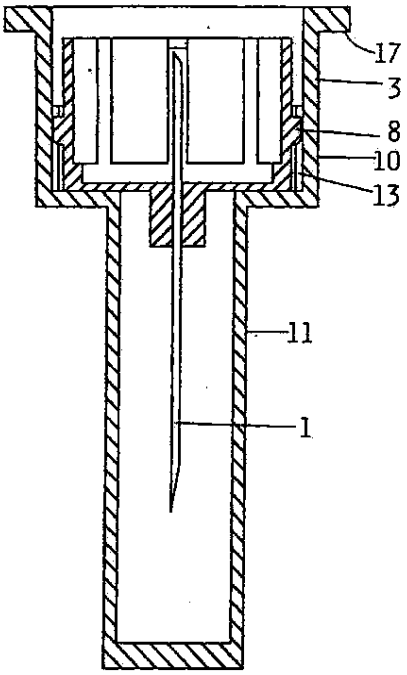


Fig. 4

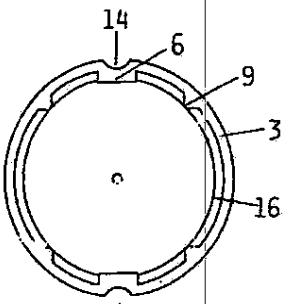


Fig. 6

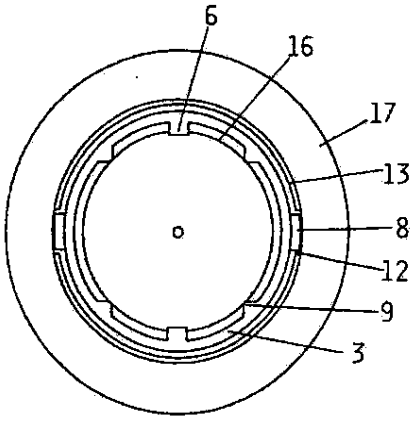


Fig. 5

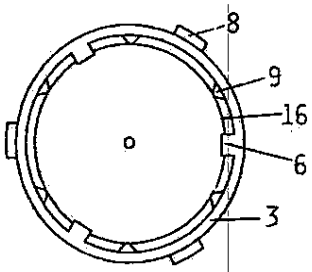


Fig. 9

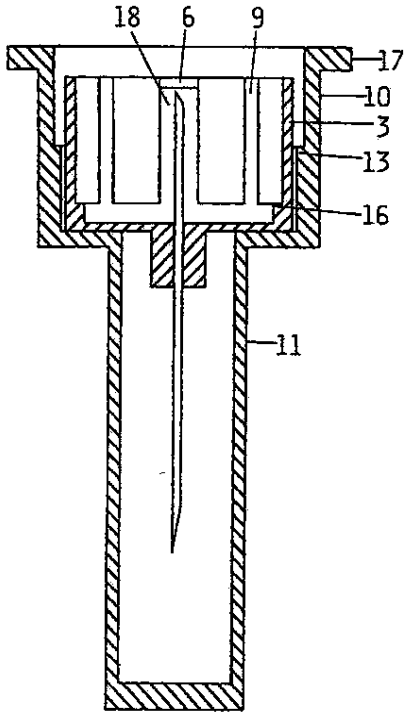


Fig. 7

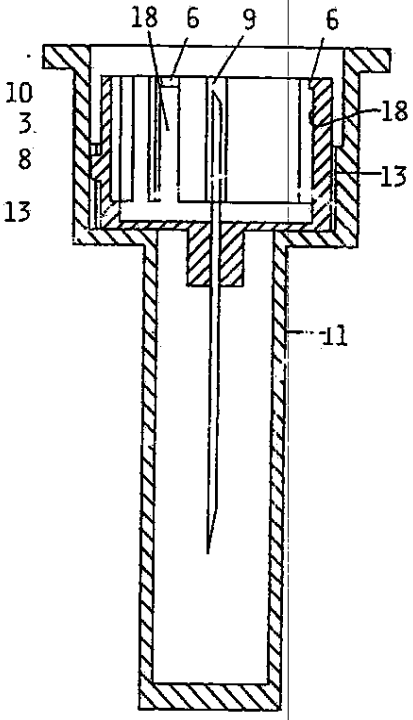
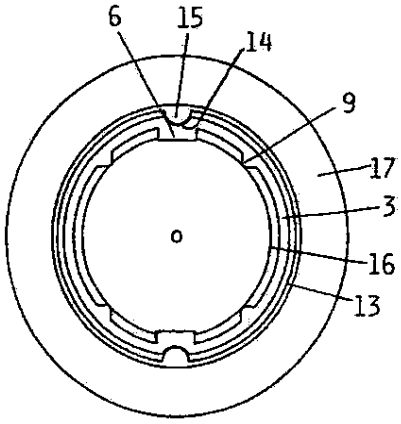


Fig. 10



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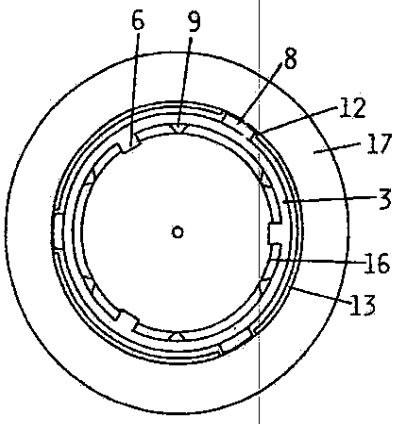


Fig. 11

8/676898

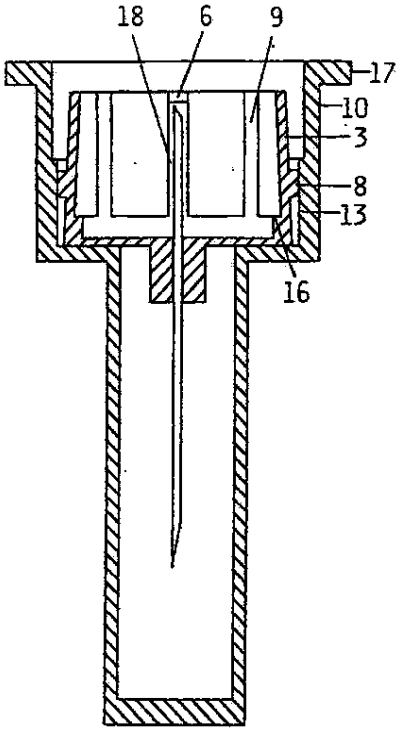


Fig. 12

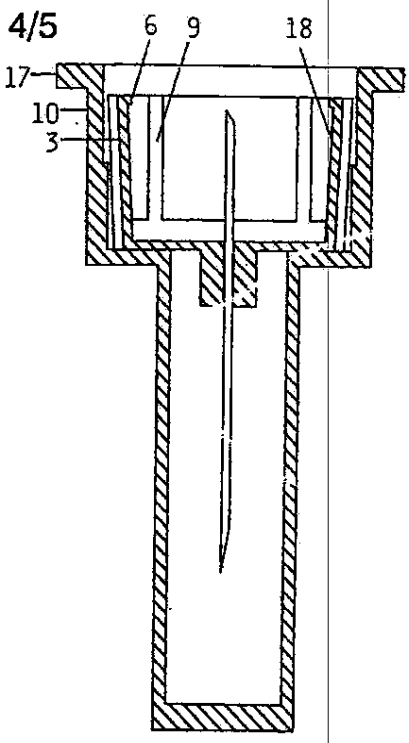
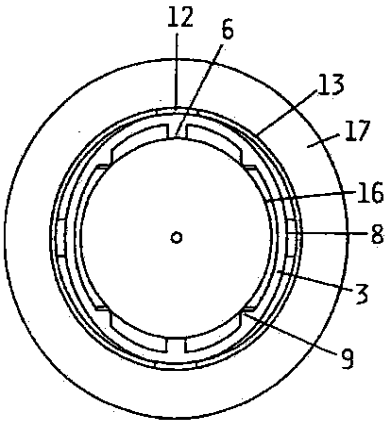


Fig. 14



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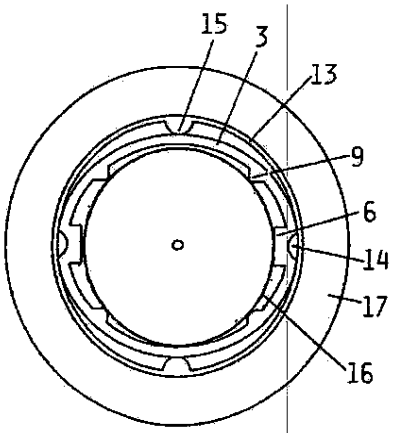

Fig. 15

8/696888

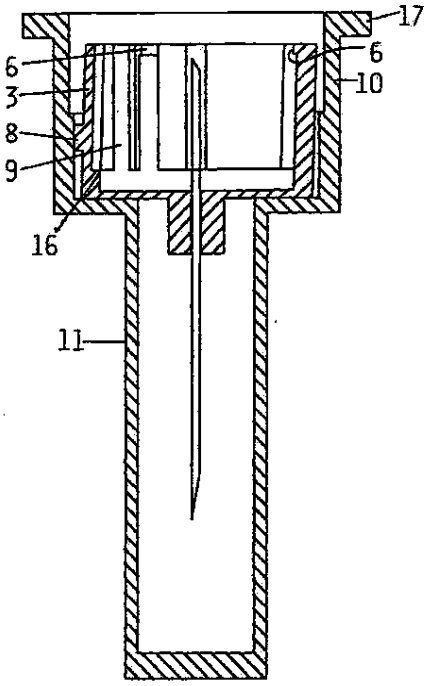

Fig. 16

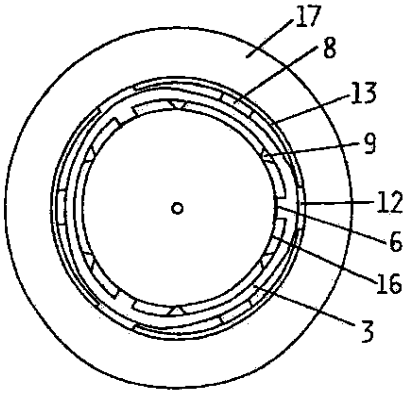

Fig. 17

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 1995

Application or Docket Number: 8696818

CLAIMS AS FILED - PART I

	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
FOR							
BASIC FEE				375.00	OR		750.00
TOTAL CLAIMS	1 minus 20 =	*	x$11=		OR	x$22=	
INDEPENDENT CLAIMS	1 minus 3 =	*	x39=		OR	x78=	
MULTIPLE DEPENDENT CLAIM PRESENT			+125=		OR	+250=	
			TOTAL		OR	TOTAL	1010

* If the difference in column 1 is less than zero, enter "0" in column 2

for Joint

CLAIMS AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT A	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x$11=		OR	x$22=	
x39=		OR	x78=	
+125=		OR	+250=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT B	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x$11=		OR	x$22=	
x39=		OR	x78=	
+125=		OR	+250=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT C	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x$11=		OR	x$22=	
x39=		OR	x78=	
+125=		OR	+250=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875
(Rev. 10/95)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Michelle Reed Mosley
Paralegal Specialist

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

(FOR USE WITH FORM PTO-875)

SERIAL NO. 8/046878 | FILING DATE

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1	1		Cancel			
2		1				
3		1				
4		2				
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49						
50						
TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS		[illegible]		1		

	*		*		*	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
51						
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98						
99						
100						
TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS						

PTO-1360 (3-78)

*MAY BE USED FOR ADDITIONAL CLAIMS OR AMENDMENTS

U.S. DEPARTMENT of COMMERCE
Patent and Trademark Office

Form PTO 1130
(REV 9/94)

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

PACE DATA ENTRY CODING SHEET

1ST EXAMINER	DATE 9/13/96
2ND EXAMINER	DATE

APPLICATION NUMBER	TYPE APPL	FILING DATE MONTH DAY YEAR	SPECIAL HANDLING	GROUP ART UNIT	CLASS	SHEETS OF DRAWING
08/696898	1	08 22 96	Ø	3306	604	5

TOTAL CLAIMS	INDEPENDENT CLAIMS	SMALL ENTITY?	FILING FEE	FOREIGN LICENSE	ATTORNEY DOCKET NUMBER
11	11	Ø	1010	4	3997.204-US

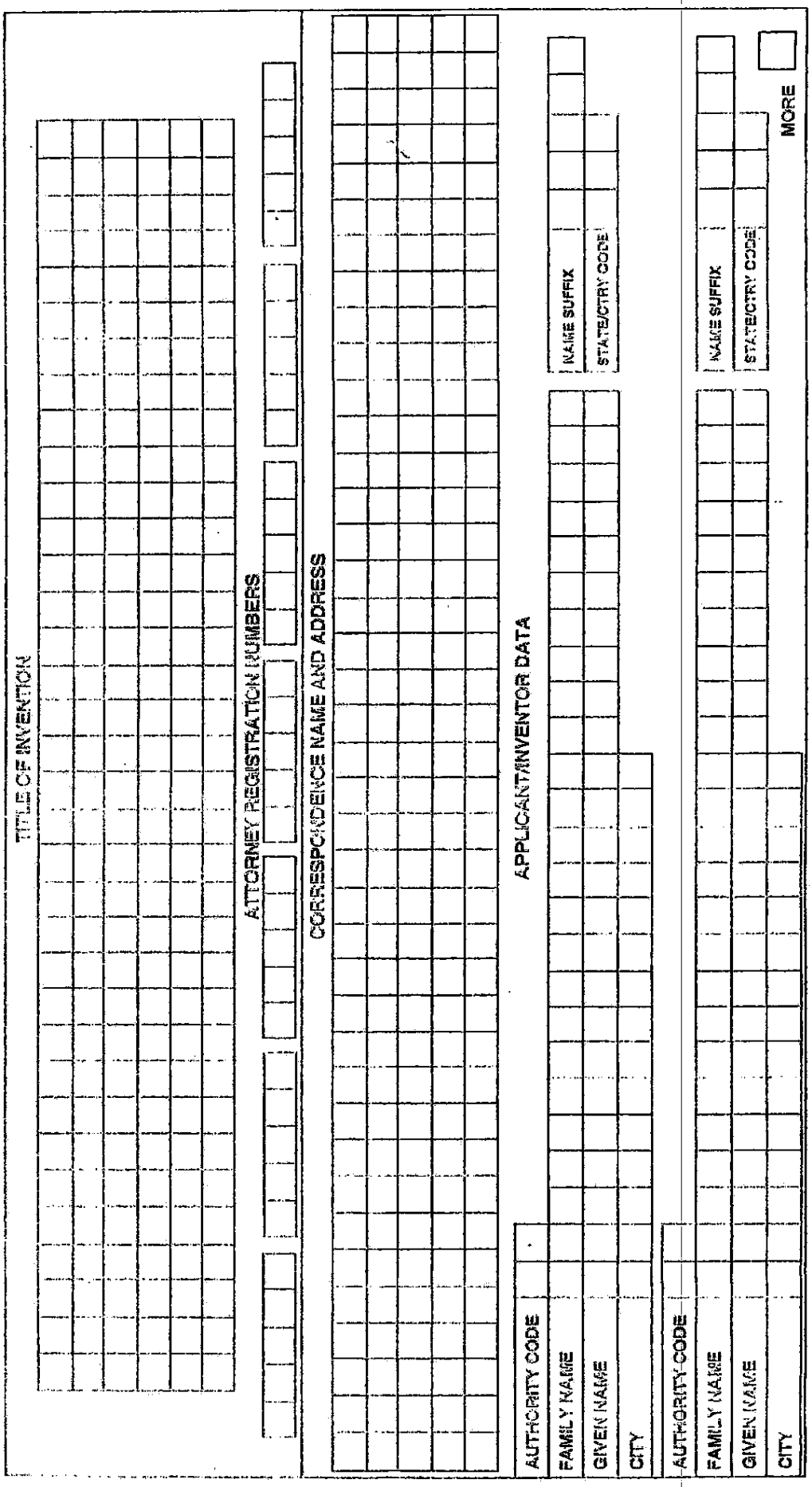
CONTINUITY DATA

CONT CODE	STATUS CODE	PARENT APPLICATION SERIAL NUMBER	PCT APPLICATION SERIAL NUMBER	PARENT PATENT NUMBER	PARENT FILING DATE MONTH DAY YEAR
			PCT /		
			PCT /		
			PCT /		
			PCT /		
			PCT /		

PCT/FOREIGN APPLICATION DATA

FOREIGN PRIORITY CLAIMED	COUNTRY CODE	PCT/FOREIGN APPLICATION SERIAL NUMBER	FOREIGN FILING DATE MONTH DAY YEAR
4	DKX	02361/94	02 28 94

☆ U.S. GPO: 1995-401-429


TITLE OF INVENTION
ATTORNEY REGISTRATION NUMBERS
CORRESPONDENCE NAME AND ADDRESS
APPLICANT/INVENTOR DATA
AUTHORITY CODE
FAMILY NAME
GIVEN NAME
CITY
NAME SUFFIX
STATE/CTRY CODE
AUTHORITY CODE
FAMILY NAME
GIVEN NAME
CITY
NAME SUFFIX
STATE/CTRY CODE
MORE

BAR CODE LABEL

U.S. PATENT APPLICATION

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT
08/696,898	08/22/96	604	3306

APPLICANT

HENNING M. EJLERSEN, VEDBAEK, DENMARK.

CONTINUING DATA********
VERIFIED THIS APPLN IS A 371 OF PCT/DK95/00085 02/27/95

FOREIGN/PCT APPLICATIONS********
VERIFIED FED REP GERMANY 0236/94 02/28/94

STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.
DKX	5	1	1	$1,010.00	3997.204-US

ADDRESS

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

TITLE

NEEDLE UNIT

This is to certify that annexed hereto is a true copy from the records of the United States Patent and Trademark Office of the application which is identified above.

By authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

Date Certifying Officer

Rec'd PCT/PTO 28 AUG 1996

FORM PTO-1390 (REV. 3-93) — U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER: 3997.204-US

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/DK95/00085	February 27, 1995	February 28, 1994

TITLE OF INVENTION
Needle Unit

APPLICANT(S) FOR DO/EO/US
Henning Munk Ejlersen

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.

2. [ ] This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.

3. [x] This express request to immediately begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).

4. [x] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. [x] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [x] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (*RO/US*).

6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. [x] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [x] have not been made and will not be made.

8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. [x] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

11. [x] Documents forming the basis for the examination of the present application
   a. [ ] the documents of the international application published by the International Bureau.
   b. [ ] the documents of the international application published by the International Bureau as amended under Article 19 PCT before the International Bureau.
      [ ] Amendments to the claims of the International Application under PCT Article 19 are transmitted herewith.
      [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
   c. [X] the documents of the international application published by the International Bureau as amended under Article 34 PCT in the procedure before the International Preliminary Examining Authority.
      [X] Amendments under Article 34 PCT which are the Annexes to the International Preliminary Examination Report (35 U.S.C. 371(c)(5)) are transmitted herewith.
      [ ] A translation of the Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 12. to 17. below concern other document(s) or information included:

12. [x] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

13. [x] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

14. [x] A FIRST Preliminary Amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.

15. [ ] A substitute specification.

16. [ ] A change of power of attorney and/or address letter.

17. [ ] Other items or information:

APPLICATION NUMBER	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
to be assigned	PCT/DK95/00085	3997.204-US

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATION
	TOTAL CLAIMS	5 -20=	0	x$22.00	$ 0.00
	INDEPENDENT CLAIMS	1 -3=	0	x$78.00	$ 0.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+$250.00	$ 0.00
	BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(4)): [ ] Search Report has been prepared by the EPO or JPO.....$ 880 [ ] International preliminary examination fee paid to USPTO (37 CFR 1.482)...$ 680 [ ] No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))..... $ 750 [x] Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....$1,010 [ ] International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2) to (4).....$ 94				$ 1,010.00
	Surcharge of $130.00 for furnishing the National fee or oath or declaration later than [ ] 20 [ ] 30 mos. from the earliest claimed priority date (37 CFR 1.492(e)).				$
			TOTAL OF ABOVE CALCULATIONS		= $ 1,010.00
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	Processing fee of $130. for furnishing the English Translation later than [ ] 20 [ ] 30 mos. from the earliest claimed priority date (37 CFR 1.492(f)).				
			TOTAL NATIONAL FEE		$
	Fee for recording the enclosed assignment (37 CFR 1.21(h)).				+
			TOTAL FEES CHARGED		$ 1,010.00

a. [ ] A check in the amount of $_____ to cover the above fees is enclosed.
b. [X] Please charge my Deposit Account No. 14-1447 in the amount of $1,010.00 to cover the above fees. A duplicate copy of this sheet is enclosed.
c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

19. The above checked items are being transmitted
a. [ ] before the 18th month publication.
b. [ ] after publication and the Article 20 communication but before 20 months from the priority date.
c. [ ] after 20 months but before 22 months (surcharge and/or processing fee included).
d. [ ] after 22 months (surcharge and/or processing fee included).
Note: Petition to revive (37 CFR 1.137(a) or (b)) is necessary if 35 U.S.C. 371 requirements submitted after 22 months and no proper demand for International Preliminary Examination was made by 19 months from the earliest claimed priority date.
e. [x] by 30 months and a proper demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
f. [ ] after 30 months but before 32 months and a proper demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date (surcharge and/or processing fee included).
g. [ ] after 32 months (surcharge and/or processing fee included).
Note: Petition to revive (37 CFR 1.137(a) or (b)) is necessary if 35 U.S.C. 371 requirements submitted after 32 months and a proper demand for International Preliminary Examination was made by 19 months from the earliest claimed priority date.

SEND ALL CORRESPONDENCE TO:
Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, New York 10174-6401
(212) 867-0123

Elias J. Lambiris
SIGNATURE

Elias J. Lambiris
NAME

33,728
REGISTRATION NUMBER

August 22, 1996
DATE

08/696898

Attorney Docket No. 3997.204-US PATENT

IN THE UNITED STATED DESIGNATED/ELECTED OFFICE (DO/EO/US)

INTERNATIONAL APPLICATION NO.: PCT/DK95/00085

INTERNATIONAL FILING DATE: February 27, 1995

PRIORITY DATE: February 28, 1994

TITLE: Needle Unit

APPLICANT(S) FOR RO/US: Henning Munk Ejlersen

EXPRESS MAIL CERTIFICATE

Box PCT
Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

Express Mail Label No. TB265585353US

Date of Deposit August 22, 1996

I hereby certify that the following attached papers or fee

1. Transmittal Letter to the DO/EO/US (in duplicate)
2. Executed Combined Declaration and Power of Attorney
3. Preliminary Amendment
4. Copy of Annexes attached to International Preliminary Examination Report
5. Recordation Form Cover Sheet
6. Assignment
7. Information Disclosure Statement
8. Form PTO 1449
9. Cited References

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Loren Hernandez
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Mailing Address:

Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10017

PCT/DK95/00085

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Washington D.C. 20231
United States of America

in its capacity as elected Office

Date of mailing (day/month/year) 25 October 1995 (25.10.95)	
International application No. PCT/DK95/00085	**Applicant's or agent's file reference** 3997-WO,EIT
International filing date (day/month/year) 27 February 1995 (27.02.95)	**Priority date** (day/month/year) 28 February 1994 (28.02.94)
Applicant EJLERSEN, Henning, Munk	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

15 September 1995 (15.09.95)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer J. Leitao
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 730.91.11

Form PCT/IB/331 (July 1992)

886999

22

PATENT COOPERATION TREA[illegible]

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3997-WO,EiT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK95/00085	International filing date (day/month/year) 27.02.1995	Priority date (day/month/year) 28.02.1994
International Patent Classification (IPC) or national classification and IPC6: A 61 M 5/32, A 61 M 5/34		
Applicant: Novo Nordisk A/S et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15.09.1995	14.05.1996
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Telex 17978 PATOREG-S Facsimile No. 08-667 72 88	Authorized officer May Hallne Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/DK95/00085

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☐ the international application as originally filed.

☒ the description, pages 1-10, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 1-4, filed with the letter of 07.03.1996,
Nos. _____, filed with the letter of _____.

☒ the drawings, ~~sheets~~/fig 1-17, as originally filed,
~~sheets~~/fig _____, filed with the demand
~~sheets~~/fig _____, filed with the letter of _____,
~~sheets~~/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, ~~sheets~~/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

Form PCT/IPEA/409 (Box I) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/DK95/00085

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-4	YES
	Claims		NO
Inventive step (IS)	Claims	1-4	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-4	YES
	Claims		NO

2. Citations and explanations

US, A, 5226894 (TERRY M. HABER ET AL), 13 July 1993 (13.07.93), column 6, line 31 - line 41, figure 17;18a,b

WO,A1, 8806463 (THE SECRETARY OF STATE FOR DEFENCE IN HER BRITANNIC MAJESTY'S GOVERNMENT OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND), 7 Sept 1988 (07.09.88), figure 1, abstract

The invention according to amended claims 1-4 relates to a magazine for storing a needle unit of the kind comprising a needle mounted in a hub having a sleeve made from a flexible material. The sleeve is snap-locked onto a connecting piece at the outlet end of a syringe by protrusions in the inner wall of the sleeve engaging recesses in the outer wall of the connecting part.

US,A,5226894 discloses a syringe with a needle unit having a connecting sleeve with an outer circumferential recess. An outer hollow body made from a flexible material is snap-locked onto the needle unit by means of at least two protrusions on its inner wall. To release the hollow body from the needle unit radial, inward pressures are exerted on specific zones of the hollow body.

WO,A1,8806463 represents prior art.

The claimed invention differs from what is known by comprising a magazine for storing and final disposing of the needle unit. The magazine comprises a compartment for the needle unit and means for exerting radial pressure on the sleeve.

Therefore, the invention is novel. It is also considered to involve an inventive step and to be industrially applicable.

Form PCT/IPEA/409 (Box V) (January 1994)

PCT/DK 95/00085

Kongeriget Danmark

Patent application No.: 0236/94

Date of filing: 28 Feb 1994

Applicant: Novo Nordisk A/S,
Novo Allé, 2880 Bagsværd, DK

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following document:

- The specification and drawings as filed with the application on the filing date indicated above.

PRIORITY DOCUMENT

Patentdirektoratet · Kongeriget Danmark ·

Erhvervsministeriet
Patentdirektoratet
TAASTRUP 17 Mar 1995

Jette Dalby
Head Clerk

/236/9428 FEB. 94

NEEDLE UNIT

The invention relates to needle units for disposable injection needles, and specifically a needle unit comprising a needle mounted in a hub having a sleeve made from a plastic material and surrounding an end of the needle in a distance from that needle, the unit being designed to be mounted at the outlet end of a syringe having a cylindric connecting piece with a recess in a plane perpendicular to the cylinder axis, which connecting piece is received in the sleeve of the needle unit.

By known needle units an inner surface of the depending sleeve is provided with an inner thread corresponding to an outer thread on the connecting piece of the syringe which the unit is intended for. The unit may then be mounted on the syringe simply by screwing it onto the connecting piece of the syringe.

However, such a screwing may be difficult to perform especially to people with reduced tactile motor function, and particularly unscrewing of a used unprotected sharp needle may be difficult if the screw connection has been carefully tightened when the unit was mounted.

Needle units are known of a type which can without screwing be mounted on a syringe which instead of a thread has a circumferential recess at the inner end of its connecting piece. Such needle units have at the inner side of their depending sleeves protrusions engaging the recess of the receiving connecting piece of the syringe. This construction is known from disposable syringes formed by snapping a needle unit onto the neck end of a cylinder ampoule, whereafter the syringe with the needle unit mounted is disposed of after use as a unity, as the needle unit cannot easily be demounted.

The object of the invention is to provide a needle unit of the snap-on type, which may easily be snapped onto a durable pen type syringe and which may easily be

dismounted from the syringe to make it possible to change the needle without having to dispose of the syringe.

This is obtained by a needle unit of the above mentioned type, which unit is characterized in that at least two protrusions are provided on the inner surface of the sleeve, the apexes of these protrusions lying on a circle having its centre in the axis of the needle unit and having when the sleeve is not deformed a radius which is smaller than the radius of the connecting piece, and that the connecting piece fits into the sleeve with a play allowing deformation of the sleeve to an extent enlarging the radius of the circle through the apexes of the protrusions to be at least equal to the radius of the connecting piece.

The sleeve may either be deformed when the connecting piece is pressed into the sleeve urging the protrusions to pass over the side wall of this connecting piece until they snap into the recesses in this wall, or the deformation may be obtained by applying a radial inward pressures on the outer side of the sleeve at zones circumferentially displaced from the position of the protrusions. By such radial pressures the sleeve will be deformed so that the protrusions will be drawn out of the recesses in the connecting piece.

To prevent the sleeve from wriggling on the connecting piece due to the play between this sleeve and connecting piece, longitudinal spacer ribs may be provided on the inner surface of the sleeve at positions lying between the protrusions and zones lying halfway between the protrusions, which zones are designed for application of radial inward pressures.

Such spacer ribs are especially indispensable when according to the invention only two protrusions are provided diametrically opposite each other.

In another appropriate embodiment of the invention three protrusions are provided 120° circumferentially spaced. To dismount this needle unit an inward pressure may

be exerted at three zones of the periphery of the sleeve, which zones must be circumferentially displaced relative to the points bearing the protrusions.

As the inward protrusions are not visible from the outer side of the sleeve, the positions of the zones for application of radial inward pressures may be indicated on the outer surface of the sleeve. The indication of the zones may appropriately be protrusions on the outer surface of the sleeve. These outward protrusions may serve further purposes as it will be described below.

The invention also concerns a magazine in which the needle unit may be stored. Such a magazine is characterized in that it comprises a compartment conforming the outer contour of the needle unit and having an access opening. The walls of this compartment may be strengthened against deformation and means for cooperation with the zones wherein radial inward pressures shall be exerted to release the hub may be provided.

The means for cooperating with the said zones may be the edge of the access opening of the magazine or of an inner strengthening of the compartment wall, which may be circular with outward recesses for accommodation of outward protrusions at the pressure zones of the sleeve when an unused needle unit is stored in the magazine, whereas engagement between the protrusions at the pressure zones of the needle unit and said edge will provide an inward pressure at said zones, when the unit is inserted in an empty magazine in a rotational position not bringing the outward protrusions on the sleeve into the outward recesses of the access opening or the strengthening of the magazine.

In another embodiment ribs may be provided on an inner cylindric wall of the compartment. In this case the sleeve must be provided with recesses in its outer cylindric wall, which recesses may accommodate said ribs when an unused needle unit is stored in the magazine. These recesses are provided in the outer wall at the positions wherein the inward protrusions of the needle hub sleeve are provided and

thereby indirectly indicates the position of the pressure zones as the zones between two recesses. When a needle unit is returned to a magazine in a rotational position wherein the ribs are not accommodated in the recesses, the ribs will exert a pressure on the zones lying between these recesses and will provide the necessary deformation of the sleeve to release the engagement between the inward protrusions of the sleeve and the recesses of the connecting piece of the syringe.

The compartment wall is strengthened to be able to impart the necessary pressure to the zones without being deformed itself. This strengthening may be obtained by the access opening being surrounded by a flange. This flange and the compartment of the magazine may be one integral plastic member.

The flange may appropriately be used as the support for a foil which fixed to the flange covers the access opening and seals the compartment

In the following a needle unit and a magazine according to the invention will be described in further details with references to the drawing, wherein

figure 1 shows a sectional view of a magazine with a needle unit according to the invention and a connecting piece for receiving the unit,

figure 2 shows schematically the needle unit in figure 1 rotated 90° and mounted on the connecting piece,

figure 3 shows the needle unit in figure 1 and 2 seen from the open end of the sleeve,

figure 4 shows a sectional side view of the needle unit of figure 1 to 3 stored in a magazine,

figure 5 shows the magazine with the stored needle unit of figure 4 seen from the access end of the magazine,

figure 6 shows another embodiment of a needle unit seen from the open end of the sleeve,

figure 7 shows a sectional side view of the needle unit of figure 6 stored in a magazine,

figure 8 shows the magazine of figure 7 with the stored unit seen from the open end of the magazine,

figure 9 shows still another embodiment of a needle unit seen from the open end of the sleeve,

figure 10 shows a sectional side view of the needle unit of figure 9 stored in a magazine,

figure 11 shows the magazine of figure 10 with the stored needle unit seen from the open end of the magazine,

figure 12 shows a sectional side view of a magazine with a needle unit according to figures 1 - 3 finally deposited in the magazine,

figure 13 shows the magazine and needle unit of figure 12 seen from the access opening of the magazine,

figure 14 shows a sectional side view of a magazine with the needle unit of figure 6 finally deposited in this magazine,

figure 15 shows the magazine of figure 14 seen from its open access end,

figure 16 shows a sectional side view of a magazine with the needle unit of figure 9 finally deposited in this magazine, and

figure 17 shows the magazine of figure 16 seen from its open access end

Figure 1 shows a needle unit stored in a magazine. The needle unit comprises a needle 1 mounted in a needle hub 2 which has a depending sleeve 3 surrounding an end of the needle 1 in some distance from this needle. The depending sleeve 3 is designed to be received on a cylindric connecting piece 4 of a syringe so that the surrounded part of the needle penetrates a not shown rubber membrane forming at least a part of an end surface 5 of the connecting piece 4.

At two diametrically opposite positions on the inner wall of the sleeve 3 inward protrusions 6 are provided. The protrusions 6 are designed to engage a circumferential recess 7 in the connecting piece 4 receiving the needle.

In figure 2 the needle unit has been rotated 90° and the receiving connecting piece 4 has been inserted into the needle unit, and it is shown how the protrusions 6 engage the recesses 7 of the connecting piece. The receiving connecting piece may be a closure part of a cylinder ampoule and the recess may be provided at the neck part of such an ampoule, but here the connecting piece is a part especially designed for cooperation with a needle unit according to the invention.

The needle hub is manufactured of a plastic material which allow some deformation of the sleeve 3 so that the diametrical distance between the apexes of the protrusions 6, which distance is smaller than the diameter of the connecting piece 4 when the sleeve is not deformed, may be increased to allow the inward protrusions 6 to pass over the side wall of the connecting piece 4 until they can snap into the recess 7 when the connecting piece 4 is pressed into the open end of the sleeve 3. During this insertion of the connecting piece 4 the open end of the sleeve 3 is deformed from having a circular appearance into an oval appearance, i.e. when the diameter connecting the inward protrusions is increased the diameter perpendicular thereto will be decreased. The not deformed sleeve must be designed to fit over the connecting piece with a play allowing this decrease.

To prevent the needle unit from wriggling due to the space between the outer wall of the connecting piece and the inner wall of the sleeve, a number of spacer ribs 9 are provide on the inner wall of the sleeve 3. These ribs will keep the connecting piece 4 centred in the sleeve 3.

In figure 3 the needle unit is seen from the open end of the sleeve. The radius of the connecting piece is indicated by a circle 16 which is formed by an edge of a guide at the inner end of the sleeve, into which guide the end of the connecting piece fits.

Axial spacer ribs 9 are provided on the inner wall of the sleeve at both sides of the inward protrusions 6 but leaving the zones 90° displaced from the inward protrusions free to be pressed axially inwards until it contacts the wall of the connection piece. As indicated in figure 2, ribs 18 are also provided extending longitudinally in the sleeve from the inward protrusions to said guide at the inner end of the sleeve. During the exertion of the radial pressure at the said zones the spacer ribs 9 abut the connecting piece and act as fulcrums assisting the lifting of the inward protrusions 6 out of engagement with the recess 7 of the connecting piece.

When it is wanted to dismount the needle unit from the connecting piece, radial inward pressures may by two fingers be imparted on the outer side of the sleeve at said zones to disconnect the snap engagement between the inward protrusions 6 and the recess 7 of the connecting piece. Therefore it is necessary that marks on the outer side of the sleeve indicate the position of such zones or indicate the positions of the inward protrusions.

In the embodiment shown in the figures 1 - 3 such marks are provided as outward protrusions 8 on the outer wall of the sleeve 3. These protrusions have another function which will be described below.

When a new and unused the needle unit is stored in a magazine as shown in figure 4 and 5, the hub with its sleeve is supported in a compartment 10 into which it fits with a play allowing the necessary deformation of the sleeve 3. The inner space of the compartment conforms the outer contour of the hub 2, i. e. longitudinal recesses are provided in the inner wall of the compartment to accommodate the outward protrusions 8 on the sleeve 3. The needle is protected by a needle cap 11 integral with the compartment 10.

To mount a new needle unit on a syringe, the user may grasp the magazine with the unit with one hand without any risk of scratching himself by the needle. With his other hand he may grasp the syringe and insert the connecting piece of this syringe

into the open end of the sleeve, the open end of which faces an open access end of the compartment of the magazine. The connection piece 4 is now pressed into the sleeve until the inward protrusions 6 of this sleeve snap into the recess 7 of this connection piece. The needle unit may now be drawn out of the magazine by the syringe.

When a used needle unit shall be disposed of, this needle unit mounted on the syringe is reinserted in the magazine but in a rotational position wherein the outward protrusions 8 of the sleeve 3 are not accommodated in the recesses 12. Thereby the outward protrusions 8 will abut an reinforcement 13 in the compartment and will be pressed radially inwards. As the outward protrusions of the sleeve are provided at the zones at which a radially inward pressure will deform the sleeve in a way bringing the inward protrusions of this sleeve out of engagement with the recesses of the connection piece, the needle unit will be disconnected from the syringe. As the outward protrusions of the sleeve are pressed into the reinforced part of the compartment, the unit will be wedged in this part and will not follow the syringe when it is retracted. A remounting of the needle unit is not possible as the sleeve remains in a deformed condition so that the inward protrusion of the sleeve will not engage the recesses of the connecting part if this part is reinserted in the sleeve. Figure 12 and 13 shows the described needle unit wedged into the magazine for final deposition.--

To ensure that the sleeve 3 and not the compartment 10 is deformed, when the used needle unit is wedged into this compartment, the compartment wall is reinforced by the provision of the part 13 having an enlarged wall thickness. As another reinforcing feature helping the compartment 10 to keep its cylindric shape, a flange 17 is provided surrounding the access opening of the compartment. The flange 17 may further act as a support for a closure. This closure may be a foil (not shown) sealed along the flange 17 to enable a sterile storage of the unused needle unit.

Figure 6 shows another embodiment of a needle unit seen from the open end of the sleeve. This embodiment differs from the one shown in figure 6 by the positions of the inward protrusions 6 being indicated by longitudinal grooves 14 in the outer surface of the sleeve 3. Figure 7 and 8 shows this unit stored in a magazine having a compartment 10, a needle cap 11, and a flange 17 as has the magazine of figure 4 and 5. The recesses 12 of the magazine of figure 4 and 5 are in figure 7 and 8 replaced by longitudinal ribs 15 which are accommodated in the grooves 14 of the needle unit when this needle unit is new and stored in the magazine. When a used needle unit is reinserted in the magazine it shall be rotated with its grooves 14 displaced 90° from the ribs 15 of the compartment. The ribs 15 will then exert the radial inward pressures on the sleeve 3 which are necessary to disengage the inward protrusions 6 of this sleeve from the recess 7 of the connecting piece. Figure 14 and 15 shows a needle unit of the kind just described wedged into its magazine for final deposition.

It shall be noticed that by embodiments wherein the inward pressures are provided by ribs in the compartment, the used needle unit must be reinserted into the compartment in a rotational position by which it is ensured that the ribs acts at the zones designed for being the objects of radially inward pressures. In embodiments using outward protrusions on the sleeve of the needle unit it is inherently ensured that pressures exerted by the protrusions abutting elements in the compartment are exerted at the zones carrying the outward protrusions. The only demand as to the rotational position when reinserted is that this position must differ from the position of the original storage with the outward protrusions accommodated in recesses.

Elements of the figures 6, 7, and 8 which corresponds to the elements of the embodiment described in figure 1 - 5 are given the same reference numerals.

Figure 9, 10, and 11 shows still another embodiment for a needle unit and the magazine for its storage and final deposition wherein three inward protrusions 6 are provided on the sleeve 3 at 120° intervals along the inner periphery thereof. Outward

protrusions 8 are provided at the zones where radially inward pressures must be exerted to release the snap engagement between the needle unit and a syringe. Spacer ribs 9 are provided in pairs at both sides of each inward protrusion leaving zones for exertion of radially inward pressures to deform the sleeve. The compartment of the magazine for storage of the new needle unit has three recesses for accommodating the outward protrusions 8 of the needle unit.

In figure 16 and 17 it is shown how a used needle unit of this kind is wedged into the magazine for final deposition.

It appears that the needle unit will always be either mounted on a syringe or stored or disposed of in a magazine.

CLAIMS

1. A needle unit comprising a needle mounted in a hub having a sleeve made from a flexible material and surrounding an end of the needle in a distance from that needle, the unit being designed to be mounted at the outlet end of a syringe having a cylindric connecting piece with a recess along a circle perpendicular to the axis of the cylindric connecting piece, which connecting piece is received in the sleeve, characterized in that at least two protrusions are provided on the inner surface of the sleeve, the apex of these protrusions lying on a circle having its centre in the axis of the needle unit and having when the sleeve is not deformed a radius which is smaller than the radius of the connecting piece, and that the connecting piece fits into the sleeve with a play allowing deformation of the sleeve to an extent enlarging the radius of the circle through the apexes of the protrusions to be equal to the radius of the connecting piece.

2. A needle unit according to claim 1, characterized in that axial ribs are provided on the inner surface of the sleeve at positions lying between the protrusions and zones lying between the protrusions, which zones are designed for application of radial inward pressures.

3. A needle unit according to claim 1 or 2, characterized in that two protrusions are provided diametrically opposite each other.

4. A needle unit according to claim 1 or 2, characterized in that three protrusions are provided 120° circumferentially spaced.

5. A needle unit according to anyone of the preceding claims, characterized in that the positions of the zones for application of radial inward pressures are indicated on the outer surface of the sleeve.

6. A needle unit according to claim 5, characterized in that the indication of the zones for application of radial inward pressures are protrusions on the outer surface of the sleeve.

7. A magazine for storing a needle unit according to anyone of the claims 1-6, characterized in that it comprises a compartment conforming the outer contour of the needle unit and having a strengthening against deformation and mean for cooperation with the zones wherein radial inward pressures shall be exerted on the sleeve of the needle unit to release this unit from a connecting piece.

8. A magazine according to claim 7, characterized in that the compartment is strengthened by its access opening being surrounded by a flange.

9. A magazine according to claim 8, characterized in that the strengthening flange and the compartment is one integral plastic member.

10. A magazine according to claim 8 or 9, characterized in that the compartment is sealed by a foil fixed to the flange surrounding the access opening of the compartment.

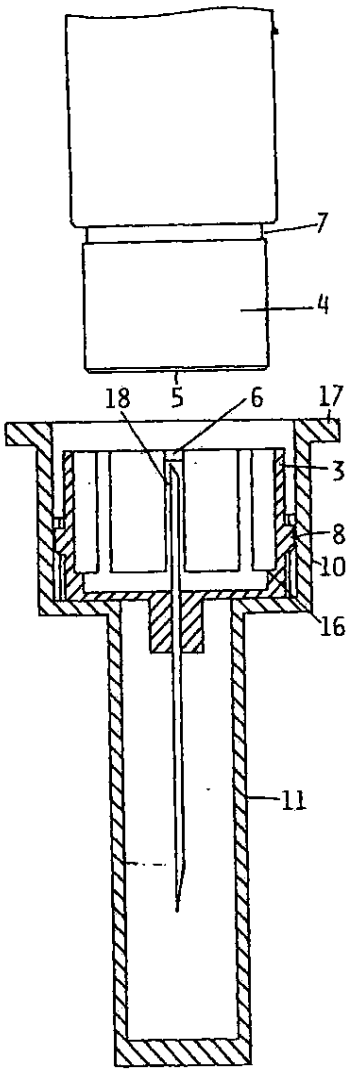


Fig. 1

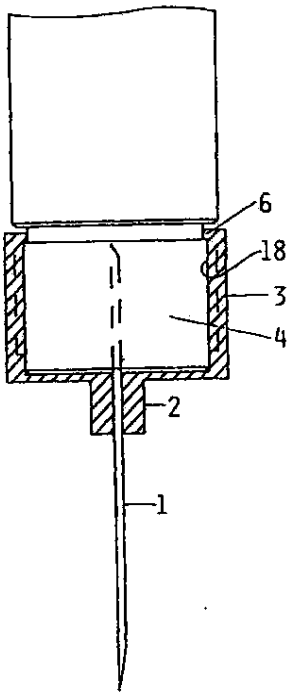


Fig. 2

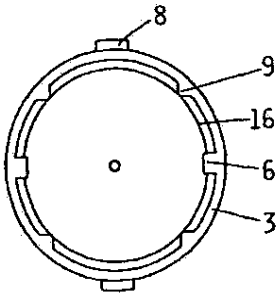


Fig. 3

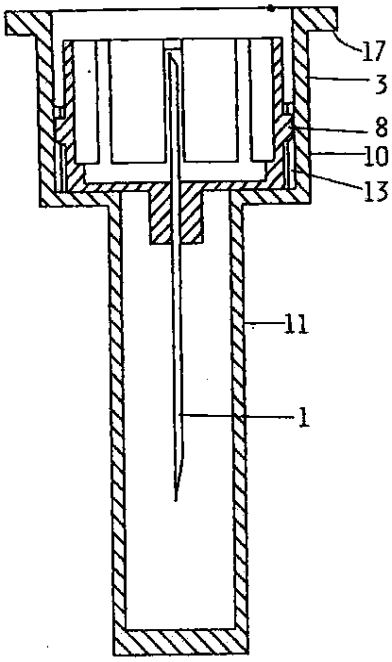


Fig. 4

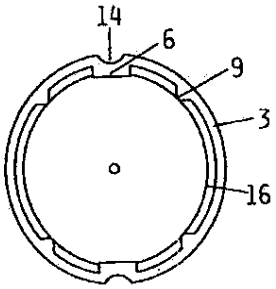


Fig. 6

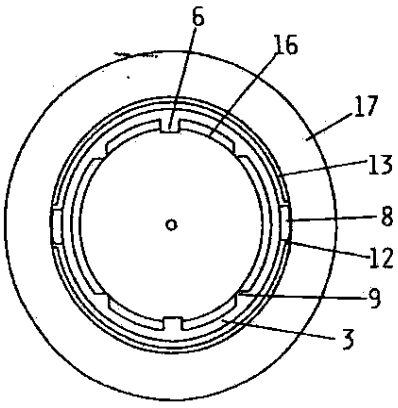


Fig. 5

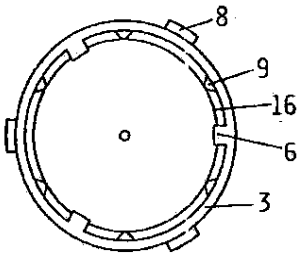


Fig. 9

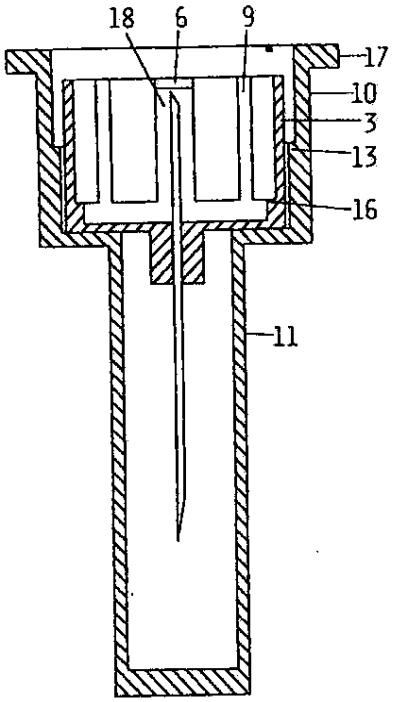


Fig. 7

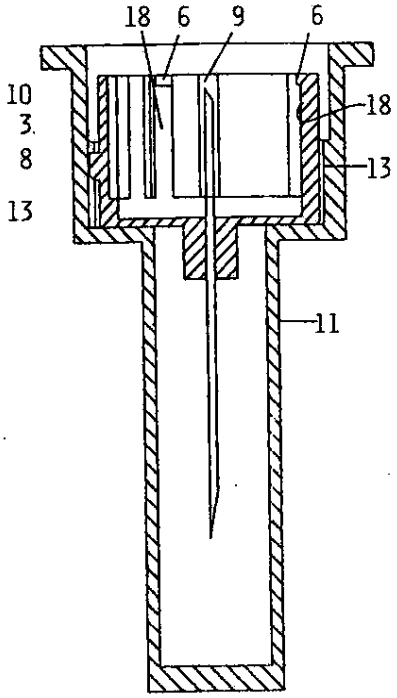


Fig. 10

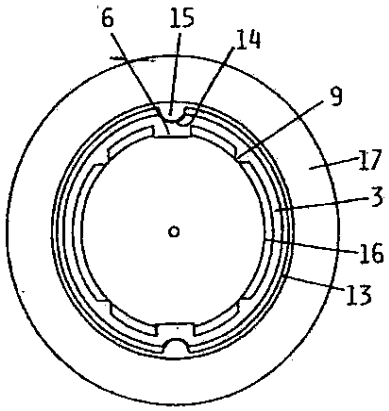


Fig. 8

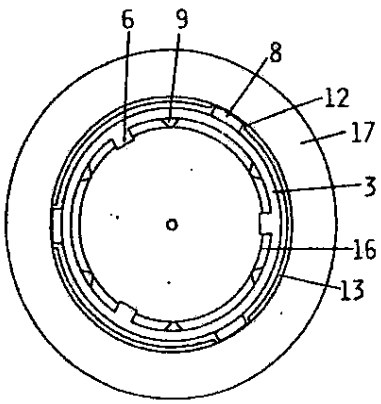


Fig. 11

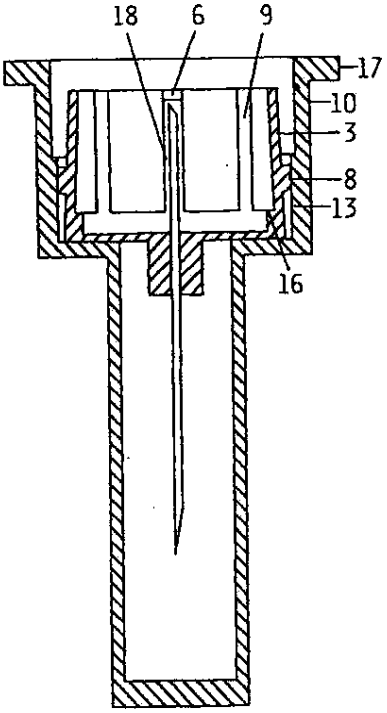


Fig. 12

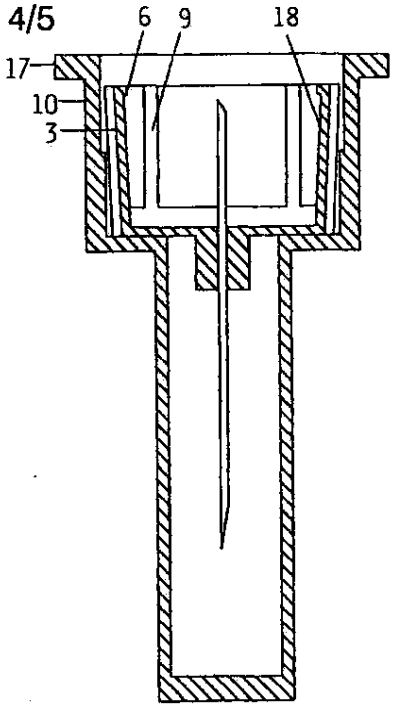


Fig. 14

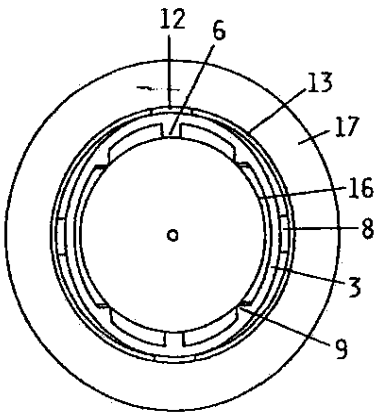


Fig. 13

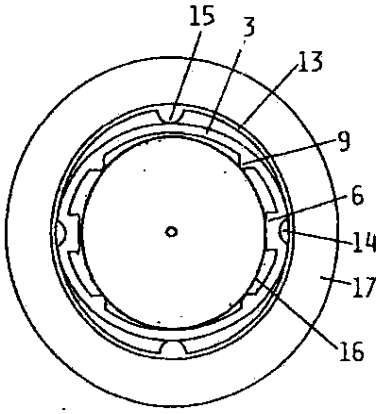


Fig. 15

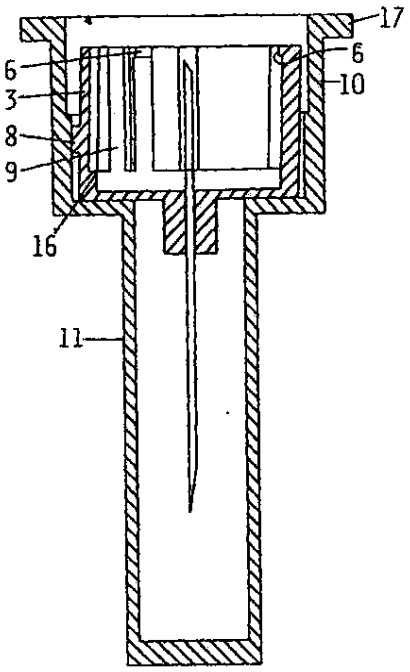


Fig. 16

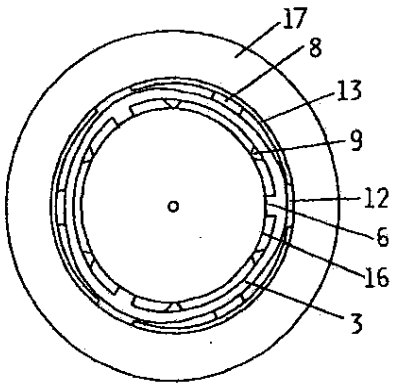


Fig. 17

PCT/DK95/00085
9 / [illegible]

CLAIMS

1. A magazine for storing and final disposing of a needle unit of the kind comprising a needle mounted in a hub having a sleeve made from a flexible material and surrounding an end of the needle in a distance from that needle, this sleeve being designed to be snap-locked onto a connecting piece at the outlet end of a syringe and so designed that the locking engagement between this sleeve and the connecting piece is released when radial inward pressures are exerted on specific zones of the sleeve, characterized in that said magazine comprises a compartment conforming an outer contour of the needle unit to freely accommodate this needle unit in a number of rotational positions, and means cooperating with said specific zones to exert a radial pressure on the sleeve in these zones when the needle unit is inserted in the magazine in other rotational positions.

2. A magazine according to claim 1, characterized in that the compartment is strengthened by an access opening being surrounded by a flange.

3. A magazine according to claim 2, characterized in that the strengthening flange and the compartment is one integral plastic member.

4. A magazine according to claim 2 or 3, characterized in that the compartment is sealed by a foil fixed to the flange surrounding the access opening of the compartment.

AMENDED SHEET

CLAIMS

1. A needle unit comprising a needle mounted in a hub having a sleeve made from a flexible material and surrounding an end of the needle in a distance from that needle, this sleeve being snap-locked onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging recesses in the outer wall of the connection piece, characterized in that the sleeve is so designed that the locking engagement between the protrusions of this sleeve and the recesses of the connecting piece is released when radial inward pressures are exerted on specific zones of the sleeve.

2. A needle unit according to claim 1, characterized in that the recesses of the connecting piece appears as a circumferential recess in the connecting piece said recess forming a circle perpendicular to the axis of the connecting piece, and the sleeve is provided with at least two protrusions at its inner side, the apex of these protrusions lying on a circle having its centre in the axis of the needle unit and having when the sleeve is not deformed a radius which is smaller than the radius of the connecting piece, and that the connecting piece fits into the sleeve with a play allowing deformation of the sleeve to an extent enlarging the radius of the circle through the apexes of the protrusions to be equal to the radius of the connecting piece.

3. A needle unit according to claim 2, characterized in that axial ribs are provided on the inner surface of the sleeve at positions lying between the protrusions and zones lying between the protrusions, which zones are designed for application of radial inward pressures.

4. A needle unit according to claim 2 or 3, characterized in that two protrusions are provided diametrically opposite each other.

5. A needle unit according to claim 2 or 3, characterized in that three protrusions are provided 120° circumferentially spaced.

6. A needle unit according to anyone of the preceding claims, characterized in that the positions of the zones for application of radial inward pressures are indicated on the outer surface of the sleeve.

7. A needle unit according to claim 6, characterized in that the indication of the zones for application of radial inward pressures are protrusions on the outer surface of the sleeve.

8. A magazine for storing a needle unit according to anyone of the claims 1-7, characterized in that it comprises a compartment conforming the outer contour of the needle unit and having a strengthening against deformation and mean for cooperation with the zones wherein radial inward pressures shall be exerted on the sleeve of the needle unit to release this unit from a connecting piece.

9. A magazine according to claim 8, characterized in that the compartment is strengthened by its access opening being surrounded by a flange.

10. A magazine according to claim 9, characterized in that the strengthening flange and the compartment is one integral plastic member.

11. A magazine according to claim 9 or 10, characterized in that the compartment is sealed by a foil fixed to the flange surrounding the access opening of the compartment.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/34	A1	(11) International Publication Number: **WO 95/23005** (43) International Publication Date: 31 August 1995 (31.08.95)

(21) International Application Number: PCT/DK95/00085

(22) International Filing Date: 27 February 1995 (27.02.95)

(30) Priority Data:
0236/94 28 February 1994 (28.02.94) DK

(71) Applicant *(for all designated States except US)*: NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsvaerd (DK).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: EJLERSEN, Henning, Munk [DK/DK]; Bueager 31, DK-2950 Vedbaek (DK).

(74) Common Representative: NOVO NORDISK A/S; Corporate Patents, Novo Allé, DK-2880 Bagsvaerd (DK).

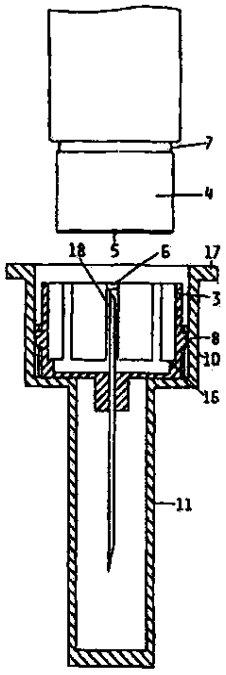
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Publisher
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: NEEDLE UNIT

(57) Abstract

A needle unit comprising a needle (1) mounted in a hub having a sleeve (3) made from a flexible material and surrounding an end of the needle (1) in a radial distance from that needle (1). The sleeve (3) is snap-locked onto a connecting piece (4) at the outlet end of a syringe by protrusions (6) on the inner wall of the sleeve (3) engaging a circumferential recess (7) in the outer wall of the connecting piece (4) and is so designed that the locking engagement between the protrusions (6) of this sleeve (3) and the recess (7) of the connecting piece (4) is released when radial inward pressures are exerted on certain zones of the outer wall of the sleeve (3). A magazine for storing the needle unit comprises a compartment (10) conforming the outer contour of the needle unit and having a strengthening against deformation and mean for cooperation with the zones wherein radial inward pressures must be exerted on the walls of the sleeve (3) of the needle unit to release this unit from a connecting piece (4).



INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 95/00085

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/34
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5226894 (TERRY M. HABER ET AL), 13 July 1993 (13.07.93), column 6, line 31 - line 41, figure 17;18a,b --	1-7
A	WO, A1, 8806463 (THE SECRETARY OF STATE FOR DEFENCE IN HER BRITANNIC MAJESTY'S GOVERNMENT OF THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND), 7 Sept 1988 (07.09.88), figure 1, abstract -- ---	1-11

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 May 1995	19 -06- 1995
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer May Hallne Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/04/95

International application No.
PCT/DK 95/00085

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5226894	13/07/93	NONE	
WO-A1- 8806463	07/09/88	AU-A- 1299188	26/09/88
		GB-A- 2223411	11/04/90

Form PCT/ISA/210 (patent family annex) (July 1992)

U.S. Appl. No. 08/691,398 DO/EO WORKSHEET International Appl No. DK95/85

Application filed by: ☐ 20 months ☑ 30 months

INTERNATIONAL APPLICATION PAPERS IN THE APPLICATION FILE

- ☑ International application (RECORD COPY)
- ☐ Article 19 amendments
- ☑ PCT/IB/331
- ☐ PCT/IPEA/416 (PCT/IPEA/416 or front)
- ☑ Annexes to 409
- ☑ Priority document(s), No. 1
- ☐ INTERNATIONAL APPLICATION ON DOUBLE SIDED PAPER (COPIES MADE)
- ☐ Request form PCT/RO/101
- ☐ PCT/IB/302
- ☑ PCT/ISA/210-Search Report SW
- ☐ Search Report references
- ☐ Other

RECEIPTS FROM THE APPLICANT (other than checked above)

- ☑ Basic National Fee (paid or authorized to charge)
- Translation of international application as filed:
  - ☐ Description
  - ☐ Claims
  - ☐ Words in the drawing figure(s)
  - ☐ Article 19 amendments
  - ☐ Annexes to 409
- ☑ Oath / Declaration
- ☐ DNA diskette
- ☑ Preliminary amendment(s) filed 22 Aug 96
- ☑ Information Disclosure Statement
- ☑ Assignment document
- ☐ Power of attorney/Change of address
- ☐ Substitute specification
- ☐ Verified small status claim
- ☐ Other

Notes:

35 U.S.C. 371 - Receipt of Request (PTO-1390) 22 AUG 1996

Date acceptable oath / declaration received 22 AUG 1996

Date complete 35 U.S.C 371 requirements met 22 AUG 1996

102(e) Date 22 AUG 1996

Date of completion of DO/EO 906 - Notification of Missing 102(e) Requirements

Date of completion of DO/EO 907 - Notification of Acceptance for 102(e) date

Date of completion of DO/EO 911 - Application accepted under 35 U.S.C. 111

Date of completion of DO/EO 905 - Notification of Missing Requirements

Date of completion of DO/EO 916 - Notification of Defective Response

Date of completion of DO/EO 903 - Notification of Acceptance 9/12/96

Date of completion of DO/EO 909 - Notification of Abandonment

WIPO Publication

Publication No. WO 95/23005

Publication Date 31 Aug 95

Publication Language English

Not Published

- ☐ U.S. only
- Designated
- ☐ EP request

Screening done by:

Screening done by: Phyllis N. Laure Legal Instrum Examiner

08 696898

Rec'd PCT/PTO 22 AUG 1996

Attorney Docket No.: 3997.204-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: to be assigned Group Art Unit: to be assigned

Filed: August 22, 1996 Examiner: to be assigned

For: Needle Unit

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

Before the above-captioned application is taken up for examination, entry of the following amendment is respectfully requested:

IN THE SPECIFICATION:

At page 1, before the first line, insert

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 35 U.S.C. 371 national application of PCT/DK95/00085 filed February 27, 1995, which is incorporated herein by reference.--

IN THE CLAIMS:

Please substitute the attached annexes to the International Preliminary Examination Report for pages 11-12 of the published PCT application WO 95/23005.

Please cancel all pending claims without prejudice or disclaimer. Please add new claims 5-9:

5. (New) A magazine for storing and final disposing of a needle unit which comprises a needle mounted in a hub having a sleeve made from a flexible material and surrounding an

end of the needle in a distance from the needle, wherein the sleeve is designed to be snap-locked onto a connecting piece at the outlet end of a syringe and is designed so that the locking arrangement between the sleeve and the connecting piece is released when radial inward pressures are exerted on specific zones of the sleeve, wherein the magazine comprises (a) a compartment conforming an outer contour of the needle unit to freely accommodate the needle unit in a number of rotational positions and (b) means cooperating with the specific zones to exert a radial pressure on the sleeve in the zones when the needle unit is inserted in the magazine in other rotational positions.

6. (New) A magazine according to claim 5, wherein the compartment is strengthened by an access opening which is surrounded by a flange.

7. (New) A magazine according to claim 6, wherein the flange and the compartment are one integral plastic member.

8. (New) A magazine according to claim 6, wherein the compartment is sealed by a foil fixed to the flange surrounding the access opening of the compartment.

9. (New) A magazine according to claim 7, wherein the compartment is sealed by a foil fixed to the flange surrounding the access opening of the compartment.

REMARKS

All pending claims have been canceled without prejudice or disclaimer. Claims 5-9 have been added and therefore are pending. Claims 5-9 are fully supported by the original claims. Therefore, no new matter is added, and entry of the amendment is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: August 22, 1996

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/696898

US APPLICATION NO.		FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/696,898		EJLERSEN H	3997204US

INTERNATIONAL APPLICATION NO.
PCT/DK95/00085

I.A. FILING DATE	PRIORITY DATE
02/27/95	02/28/94

5611

STEVE T. ZELSON
NOVO NORDISK OF NORTH AMERICA
405 LEXINGTON AVENUE, SUITE 6400
NEW YORK, NY 10174-6401

DATE MAILED: 09/13/96

NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495

1. The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as ☐ a Designated Office (37 CFR 1.494), ☑ an Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

2. The United States Application Number assigned to the application is shown above and the relevant dates are:

22 AUG 1996 — 35 U.S.C. 102(e) DATE

22 AUG 1996 — DATE OF RECEIPT OF 35 U.S.C. 371 REQUIREMENTS

3. ☑ A request for immediate examination under 35 U.S.C. 371(f) was received on 22 AUG 1996 and the application will be examined in turn.

4. The following items have been received:
- ☑ U.S. Basic National Fee.
- ☑ Copy of the international application in:
  - ☐ a non-English language.
  - ☑ English.
- ☐ Translation of the international application into English.
- ☑ Oath or Declaration of inventors(s) for DO/EO/US.
- ☐ Copy of Article 19 amendments. ☐ Translation of Article 19 amendments into English. The Article 19 amendments ☐ have ☐ have not been entered.
- ☑ The International Preliminary Examination Report in English and its Annexes, if any.
- ☐ Translation of Annexes to the International Preliminary Examination Report into English. The Annexes ☑ have ☐ have not been entered.
- ☑ Preliminary amendment(s) filed 22 AUG 1996 and _____.
- ☑ Information Disclosure Statement(s) filed 22 AUG 1996 and _____.
- ☑ Assignment document.
- ☐ Power of Attorney and /or Change of Address.
- ☐ Substitute specification filed _____.
- ☐ Verified Statement Claiming Small Entity Status.
- ☑ Priority Document.
- ☑ Copy of the Search Report ☐ and copies of the references cited therein.
- ☐ Other:

A Filing Receipt (PTO-103X) will be issued for the present application in due course. Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

Michelle Reed Mosley
Paralegal Specialist
Telephone (703) 305-3735

FORM PCT/DO/EO/903 (May 1993)

8/646898 PTO 22 AUG 1996 II 2½

Attorney Docket No.: 3997.204-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: to be assigned Group Art Unit: to be assigned

Filed: to be assigned Examiner: to be assigned

For: Needle Unit

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the examination of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

1. PCT WO 88/06463
2. USP 5,226,894

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record

therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Respectfully submitted,

Date: August 22, 1996

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Sheet 1 of 1

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Atty. Docket No. 3997.204-US

Serial No. 08/696,898 to be assigned

Applicant Henning Munk Ejlersen

Filing Date 8/22/96 ~~to be assigned~~

Group 3306 ~~to be assigned~~

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
RS		5,226,894	07/13/93	Haber et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
RS		88/06463	09/07/88	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER Ron Shapiro

DATE CONSIDERED 9/26/97

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Rec'd PCT/PTO 20 SEP 1996

SUCO PC #3 10/11/96

Attorney Docket No.: 3997.204-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: 08/696,898 Group Art Unit: to be assigned

Filed: August 22, 1996 Examiner: to be assigned

For: Needle Unit

SUBMISSION OF FORMAL DRAWINGS

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

Applicants submit herewith 5 sheets of formal drawings, containing 16 Figures for the above-captioned application. The formal drawings should be substituted for the corresponding sheets of informal drawings of the originally filed application.

Respectfully submitted,

Date: September 17, 1996

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

20 SEP 1996 #3 6/11/96

Attorney Docket No.: 3997.204-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: 08/696,898 Group Art Unit: to be assigned

Filed: August 22, 1996 Examiner: to be assigned

For: Needle Unit

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Submission of Formal Drawings
2. 5 Sheets of Formal Drawings

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Attn: Official Draftsman
Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

on September 17, 1996.

Elias J. Lambiris
(name of person mailing paper)

(signature of person mailing paper)

08/696898

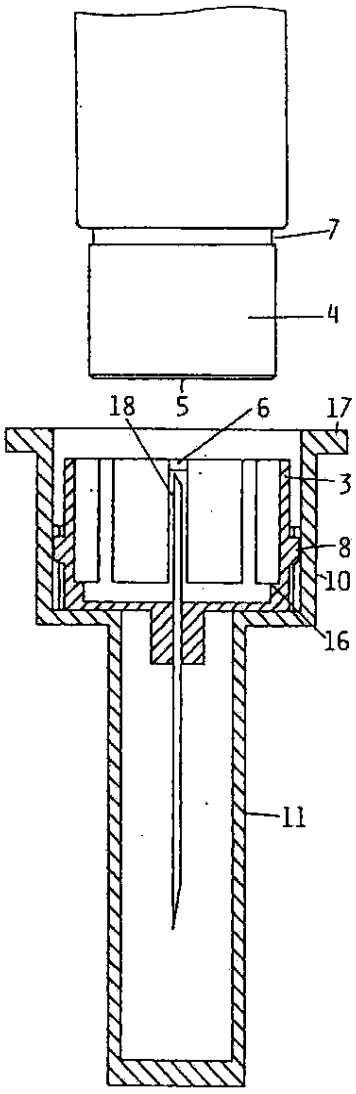


Fig. 1

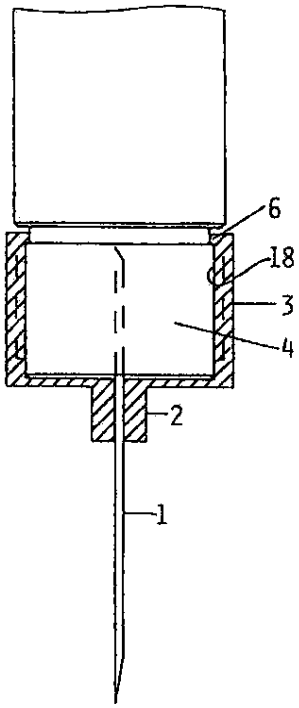


Fig. 2

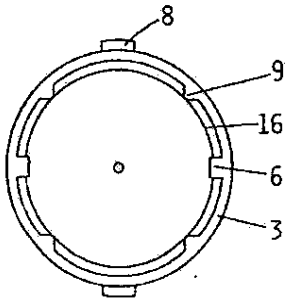


Fig. 3

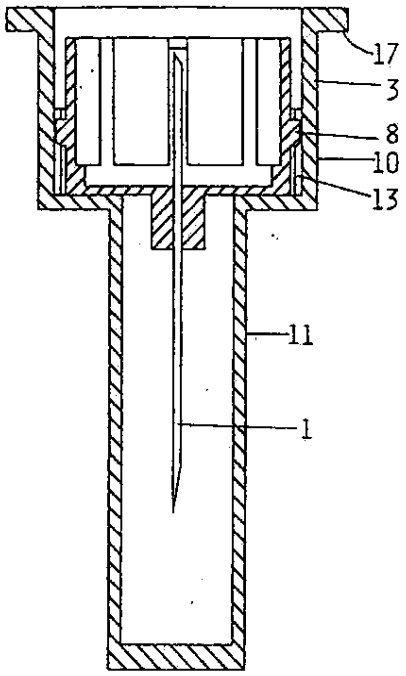


Fig. 4

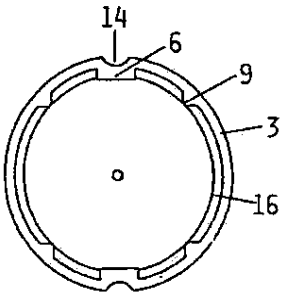


Fig. 6

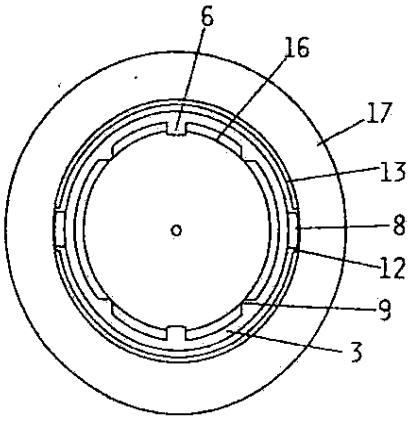


Fig. 5

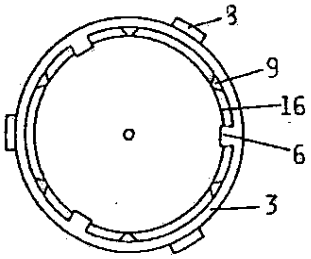


Fig. 9

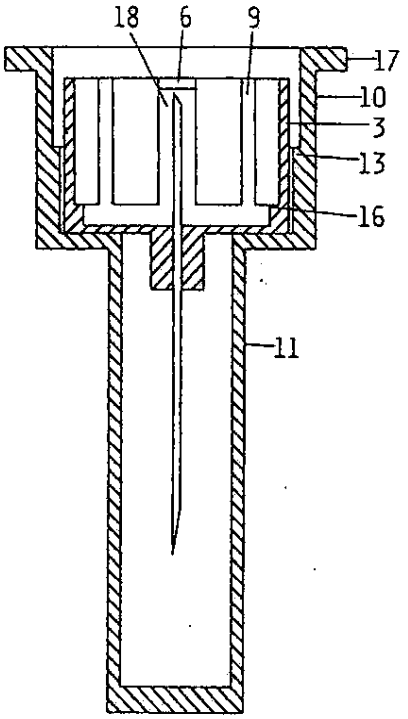


Fig. 7

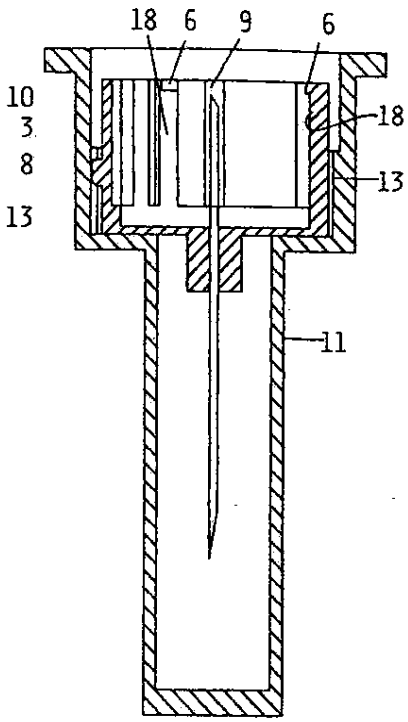


Fig. 10

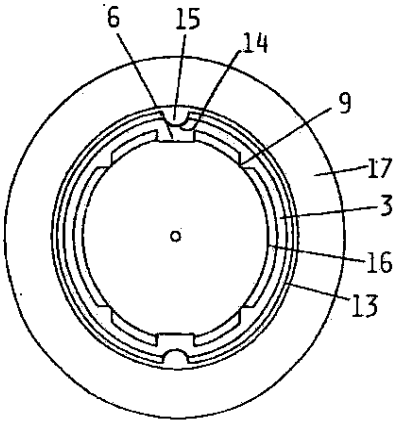


Fig. 8

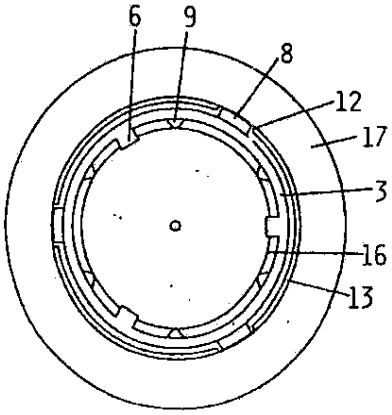


Fig. 11

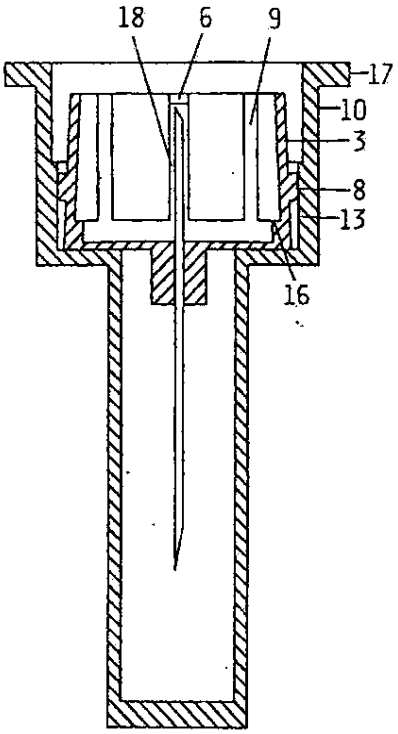


Fig. 12

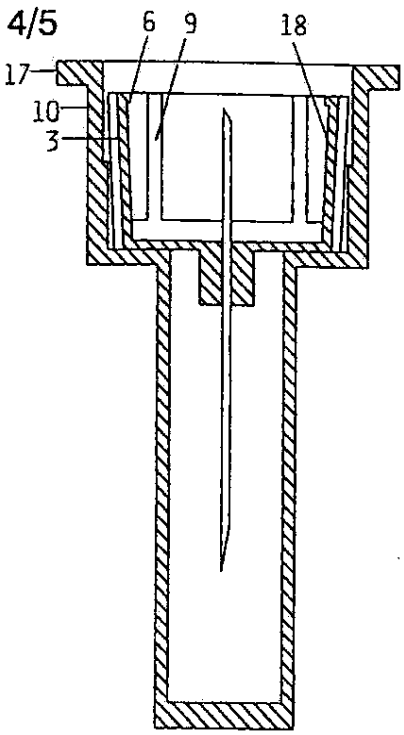


Fig. 14

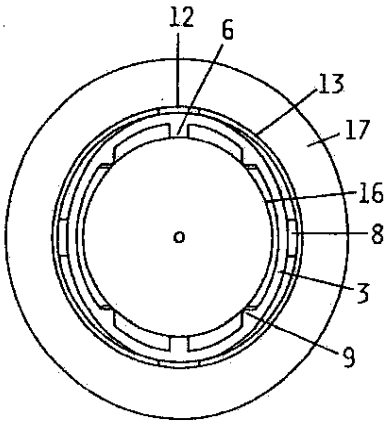


Fig. 13

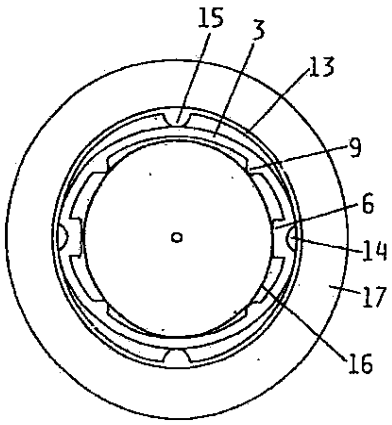


Fig. 15

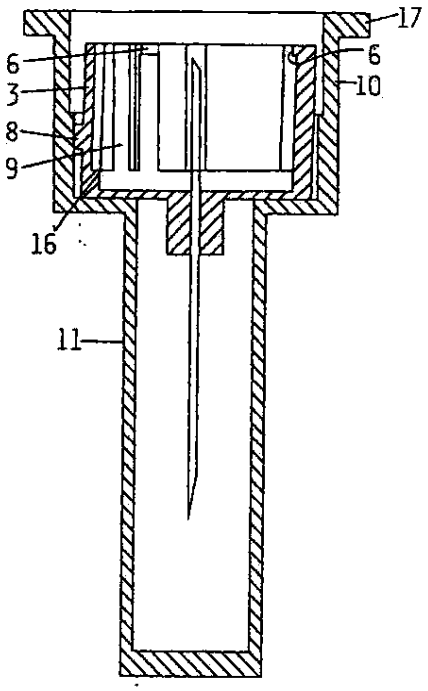


Fig. 16

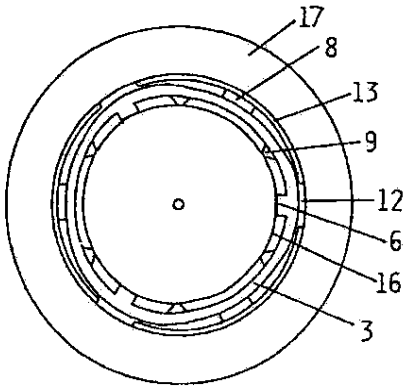


Fig. 17

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/696,898	08/22/96	EJLERSEN	H 3997.204-US

EXAMINER

33M1/1009

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

ART UNIT	PAPER NUMBER
3306	4

DATE MAILED: 10/09/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 5-9 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 5-9 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the foil fixed to the flange surrounding the access opening of claims 8 and 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. The drawings are objected to because in figure 10, numerals 10, 3, 8 and 13 lack reference lines to indicate each part intended in the figure. Correction is required.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

5. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

(a) Title of the Invention.
(b) Cross-References to Related Applications (if any).
© Statement as to rights to inventions made under Federally-sponsored research and development (if any).
(d) Background of the invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97-1.99.
(e) Summary of the Invention.
(f) Brief Description of the Drawing.
(g) Description of the Preferred Embodiment(s).
(h) Claim(s).
(I) Abstract of the Disclosure.

Applicant needs to add the headings to each section of the specification.

Claim Rejections - 35 USC § 112

6. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite because it is unclear if applicant intends to claim the combination of a needle unit and a magazine or a magazine alone. The body of the claim makes positive recitation to the zones that were defined as part of the needle unit. This recitation is the function of the cooperating means. It is unclear if the claim is intended to be a "Jepson type"

claim where the improvement is the magazine with the needle unit and its related parts as the well known structure.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Poncy '730.

Poncy discloses the magazine at 14 having a compartment conforming to the needle to freely accommodate the needle unit in a number of rotational positions and a cooperating means as the member 32 or the guide rails 60. A needle unit is shown at 16. Poncy further discloses the magazine having a plastic integral flange 44 located thereon.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poncy in view of Meierhoefer '044.

Poncy discloses the syringe magazine substantially as claimed except for the foil seal fixed to and surrounding the access opening of the magazine compartment. Meierhoefer discloses that it is well known to utilize tear-cap seal made of foil used to seal the opening of the syringe to keep the contents thereof in a sterile environment. It would have been obvious to one of ordinary skill in the art to construct the syringe needle housing of Poncy with a tear-cap seal made of foil as taught by Meierhoefer since it is well desired in the medical art and syringe art to keep the instruments as sterile as possible before use to avoid any bacterial migration, etc. Each element acting in the new environment as it did in the old is evidence of obviousness.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note the prior art shows different forms of needle magazines utilizing caps or seals at the ends thereof for protection and for keeping the devices sterile.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Stright whose telephone number is (703) 308-2113. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached on (703) 308-0871. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Ronald K. Stright, Jr.
Patent Examiner
Group 3300
September 26, 1997

TO SEPARATE, FOLD TOP AND BOTTOM EDGES, SNAP--APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

NOTICE OF REFERENCES CITED

SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
08/696,898	3306	4

APPLICANT(S): Ejlersen

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	3989044	11/2/76	Meierhoefer	604	192	
	B	4961730	10/9/90	Poncy	604	263	
	C	4772272	9/20/88	McFarland	604	263	
	D	5312370	5/17/94	Talonn etal	604	198	1/29/90
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R

S

T

U

EXAMINER: Ron Stright

DATE: [redacted] 9/26/97

* A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, section 707.05 (a).)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/696,898

US APPLICATION NO.		FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/696,898		EJLERSEN H	3997204US

INTERNATIONAL APPLICATION NO
PCT/DK95/00085

371 FILING DATE	PRIORITY DATE
02/27/95	02/28/94

5611

STEVE T. ZELSON
NOVO NORDISK OF NORTH AMERICA
405 LEXINGTON AVENUE, SUITE 6400
NEW YORK, NY 10174-6401

DATE MAILED: 09/13/96

NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495

1. The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as ☐ a Designated Office (37 CFR 1.494), ☑ an Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

2. The United States Application Number assigned to the application is shown above and the relevant dates are:

22 AUG 1996 — 35 U.S.C. 102(e) DATE

22 AUG 1996 — DATE OF RECEIPT OF 35 U.S.C. 371 REQUIREMENTS

3. ☑ A request for immediate examination under 35 U.S.C. 371(f) was received on 22 AUG 1996 and the application will be examined in turn.

4. The following items have been received:
- ☑ U.S. Basic National Fee.
- ☑ Copy of the international application in:
  - ☐ a non-English language.
  - ☑ English.
- ☐ Translation of the international application into English.
- ☑ Oath or Declaration of inventors(s) for DO/EO/US.
- ☐ Copy of Article 19 amendments. ☐ Translation of Article 19 amendments into English.
  The Article 19 amendments ☐ have ☐ have not been entered.
- ☑ The International Preliminary Examination Report in English and its Annexes, if any.
- ☐ Translation of Annexes to the International Preliminary Examination Report into English.
  The Annexes ☑ have ☐ have not been entered.
- ☑ Preliminary amendment(s) filed 22 AUG 1996 and _____.
- ☑ Information Disclosure Statement(s) filed 22 AUG 1996 and _____.
- ☑ Assignment document.
- ☐ Power of Attorney and /or Change of Address.
- ☐ Substitute specification filed _____.
- ☐ Verified Statement Claiming Small Entity Status.
- ☑ Priority Document.
- ☑ Copy of the Search Report ☐ and copies of the references cited therein.
- ☐ Other:

A Filing Receipt (PTO-103X) will be issued for the present application in due course. Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

Michelle Reed Mosley
Paralegal Specialist
Telephone (703) 305-3735

FORM PCT/DO/EO/903 (May 1993)

8/646898 PTO 22 AUG 1996

Attorney Docket No.: 3997.204-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: to be assigned Group Art Unit: to be assigned

Filed: to be assigned Examiner: to be assigned

For: Needle Unit

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the examination of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

1. PCT WO 88/06463
2. USP 5,226,894

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record

therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Respectfully submitted,

Date: August 22, 1996

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Sheet 1 of 1

FORM PTO-1449 (Rev. 2-32) | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | Atty. Docket No. 3997.204-US | Serial No. 08/696,898 ~~to be assigned~~

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Applicant: Henning Munk Ejlersen

Filing Date ~~to be assigned~~ 8/22/96 | Group ~~to be assigned~~ 3306

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
RS		5,226,894	07/13/93	Haber et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
RS		88/06463	09/07/88	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER: Ron Stright | DATE CONSIDERED: 9/26/97

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

5000 PC
#3
10/11/96

Attorney Docket No.: 3997.204-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: 08/696,898 Group Art Unit: to be assigned

Filed: August 22, 1996 Examiner: to be assigned

For: Needle Unit

SUBMISSION OF FORMAL DRAWINGS

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

Applicants submit herewith 5 sheets of formal drawings, containing 16 Figures for the above-captioned application. The formal drawings should be substituted for the corresponding sheets of informal drawings of the originally filed application.

Respectfully submitted,

Date: September 17, 1996

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

20 SEP 1996

#3

PATENT 6/11/96

Attorney Docket No.: 3997.204-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: 08/696,898 Group Art Unit: to be assigned

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Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Submission of Formal Drawings
2. 5 Sheets of Formal Drawings

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Attn: Official Draftsman
Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

on September 17, 1996.

Elias J. Lambiris
(name of person mailing paper)

(signature of person mailing paper)

08/696898

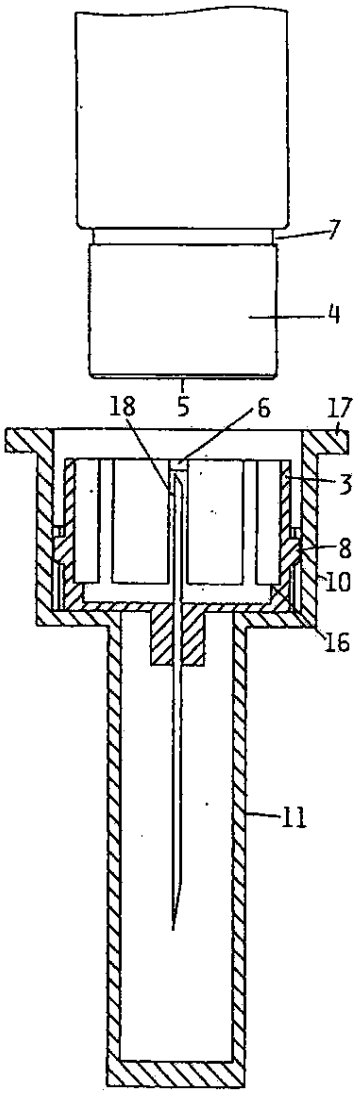


Fig. 1

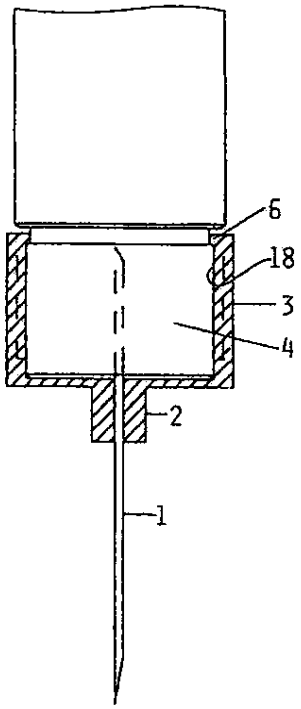
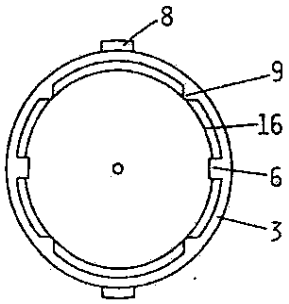


Fig. 2



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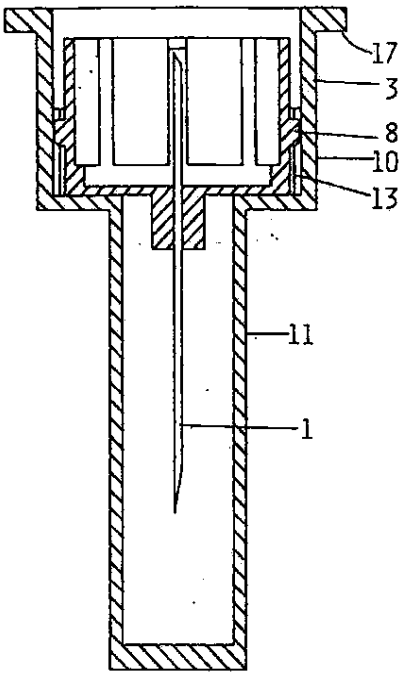

Fig. 4

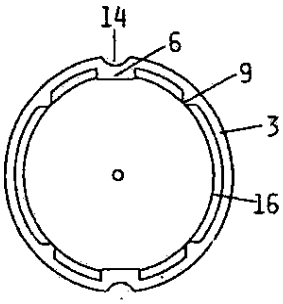

Fig. 6

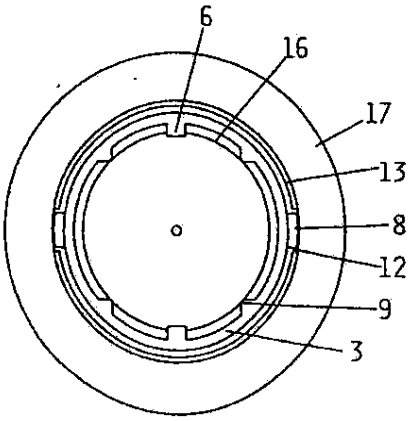

Fig. 5

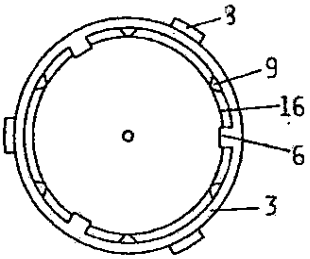

Fig. 9

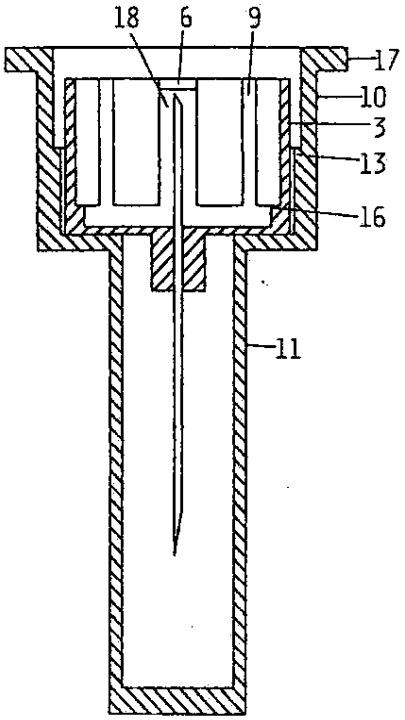

Fig. 7

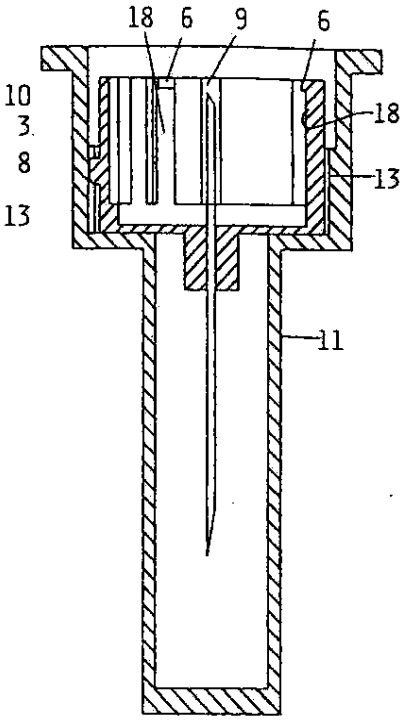

Fig. 10

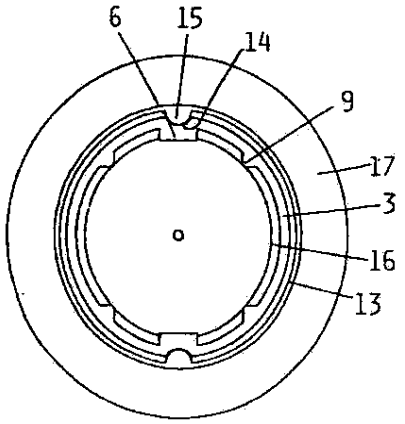

Fig. 8

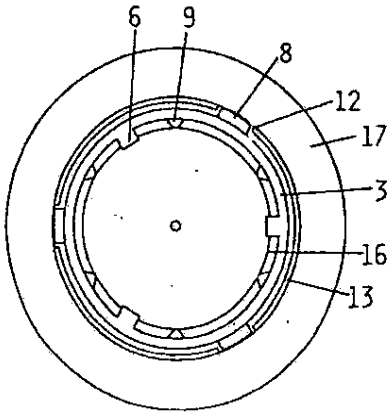

Fig. 11

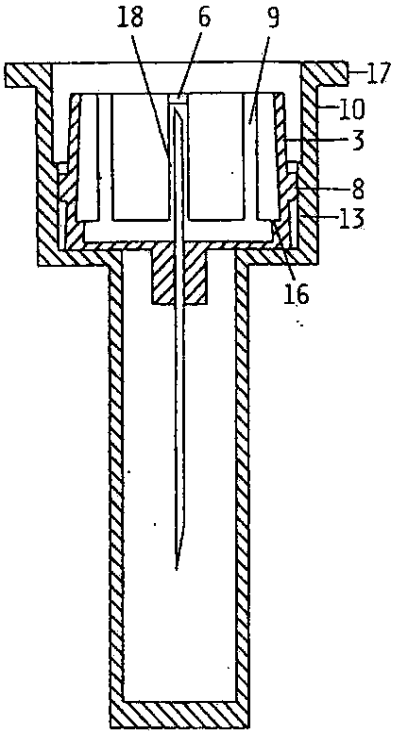

Fig. 12

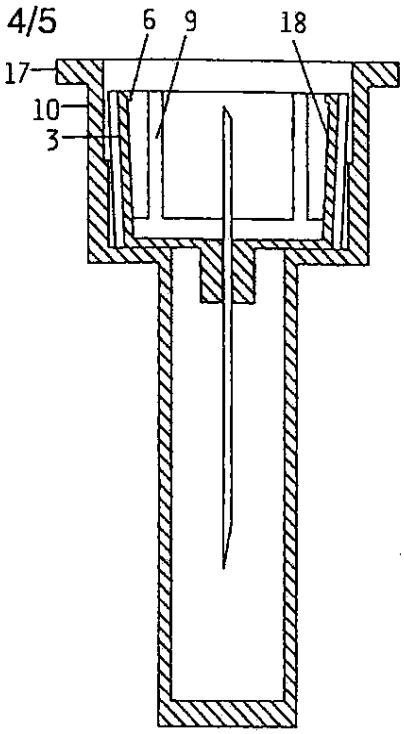

Fig. 14

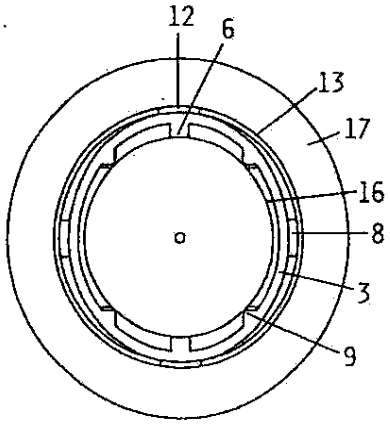

Fig. 13

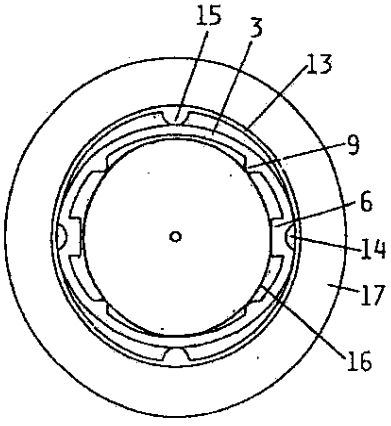

Fig. 15

5/5

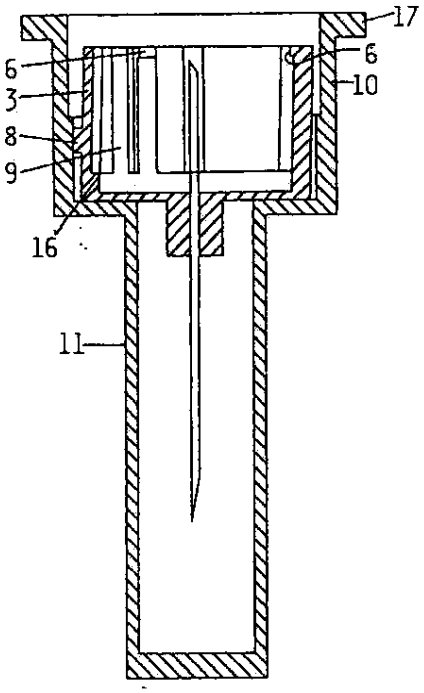

Fig. 16

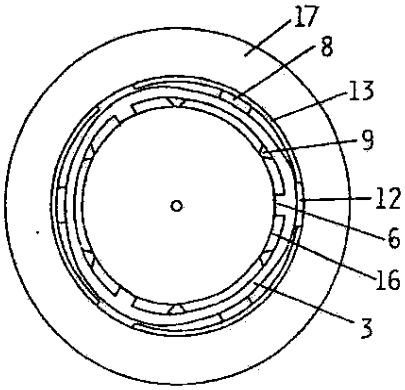

Fig. 17

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/696,898	08/22/96	EJLERSEN	H 3997.204-US

EXAMINER

33M1/1009

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

ART UNIT	PAPER NUMBER
3306	4

DATE MAILED: 10/09/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 5-9 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 5-9 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the foil fixed to the flange surrounding the access opening of claims 8 and 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. The drawings are objected to because in figure 10, numerals 10, 3, 8 and 13 lack reference lines to indicate each part intended in the figure. Correction is required.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

5. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

(a) Title of the Invention.
(b) Cross-References to Related Applications (if any).
© Statement as to rights to inventions made under Federally-sponsored research and development (if any).
(d) Background of the invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97-1.99.
(e) Summary of the Invention.
(f) Brief Description of the Drawing.
(g) Description of the Preferred Embodiment(s).
(h) Claim(s).
(I) Abstract of the Disclosure.

Applicant needs to add the headings to each section of the specification.

Claim Rejections - 35 USC § 112

6. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite because it is unclear if applicant intends to claim the combination of a needle unit and a magazine or a magazine alone. The body of the claim makes positive recitation to the zones that were defined as part of the needle unit. This recitation is the function of the cooperating means. It is unclear if the claim is intended to be a "Jepson type"

claim where the improvement is the magazine with the needle unit and its related parts as the well known structure.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Poncy '730.

Poncy discloses the magazine at 14 having a compartment conforming to the needle to freely accommodate the needle unit in a number of rotational positions and a cooperating means as the member 32 or the guide rails 60. A needle unit is shown at 16. Poncy further discloses the magazine having a plastic integral flange 44 located thereon.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poncy in view of Meierhoefer '044.

Poncy discloses the syringe magazine substantially as claimed except for the foil seal fixed to and surrounding the access opening of the magazine compartment. Meierhoefer discloses that it is well known to utilize tear-cap seal made of foil used to seal the opening of the syringe to keep the contents thereof in a sterile environment. It would have been obvious to one of ordinary skill in the art to construct the syringe needle housing of Poncy with a tear-cap seal made of foil as taught by Meierhoefer since it is well desired in the medical art and syringe art to keep the instruments as sterile as possible before use to avoid any bacterial migration, etc. Each element acting in the new environment as it did in the old is evidence of obviousness.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note the prior art shows different forms of needle magazines utilizing caps or seals at the ends thereof for protection and for keeping the devices sterile.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Stright whose telephone number is (703) 308-2113. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached on (703) 308-0871. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Ronald K. Stright, Jr.
Patent Examiner
Group 3300
September 26, 1997

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP–APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

NOTICE OF REFERENCES CITED

SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
08/696,898	3306	4

APPLICANT(S): Ejlersen

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	3989044	11/2/76	Meierhoefer	604	192	
	B	4961730	10/9/90	Poncy	604	263	
	C	4772272	9/20/88	McFarland	604	263	
	D	5312370	5/17/94	Talonn et al	604	198	1/29/90
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R

S

T

U

EXAMINER: Ron Stright DATE: 9/26/97

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

Form PTO 948 (Rev. 10-94) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 8/696898

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

PTO Draftpersons review all originally filed drawings regardless of whether they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

The drawings filed (insert date) 8/22/96 are
A. _____ not objected to by the Draftsperson under 37 CFR 1.84 or 1.152.
B. _____ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this Notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - ___ Not black solid lines. Fig(s)_____
   - ___ Color drawings are not acceptable until petition is granted. Fig(s) _____
2. PHOTOGRAPHS. 37 CFR 1.84(b)
   - ___ Photographs are not acceptable until petition is granted. Fig(s) _____
   - ___ Photographs not properly mounted (must use bristol board or photographic double-weight paper). Fig(s)_____
   - ___ Poor quality (half-tone). Fig(s)_____
3. GRAPHIC FORMS. 37 CFR 1.84 (d)
   - ___ Chemical or mathematical formula not labeled as separate figure. Fig(s)_____
   - ___ Group of waveforms not presented as a single figure, using common vertical axis with time extending along horizontal axis. Fig(s)_____
   - ___ Individuals waveform not identified with a separate letter designation adjacent to the vertical axis. Fig(s)_____
4. TYPE OF PAPER. 37 CFR 1.84(c)
   - ___ Paper not flexible, strong, white, smooth, nonshiny, and durable. Sheet(s)_____
   - ___ Erasures, alterations, overwritings, interlineations, cracks, creases, and folds copy machine marks not accepted. Fig(s) _____
   - ___ Mylar, velum paper is not acceptable (too thin). Fig(s) _____
5. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
   - 21.6 cm. by 35.6 cm. (8 1/2 by 14 inches)
   - 21.6 cm. by 33.1 cm. (8 1/2 by 13 inches)
   - 21.6 cm. by 27.9 cm. (8 1/2 by 11 inches)
   - 21.0 cm. by 29.7 cm. (DIN size A4)
   - ___ All drawing sheets not the same size. Sheet(s)_____
   - ___ Drawing sheet not an acceptable size. Sheet(s) _____
6. MARGINS. 37 CFR 1.84(g): Acceptable margins:

Paper size

	21.6 cm. X 35.6 cm. (8 1/2 X 14 inches)	21.6 cm X 33.1 cm. (8 1/2 X 13 inches)	21.6 cm. X 27.9 cm. (8 1/2 X 11 inches)	21.0 cm. X 29.7 cm. (DIN Size A4)
T	5.1 cm. (2")	2.5 cm. (1")	2.5 cm. (1")	2.5cm.
L	.64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	2.5 cm.
R	.64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.5 cm.
B	.64 cm. (1/4")	.64 cm. (1/4")	.64 cm. (1/4")	1.0 cm.

Margins do not conform to chart above.
Sheet(s)_____
___Top (T) ___Left (L) ___Right (R) ___Bottom (B)

7. VIEWS. 37 CFR 1.84(h)
   REMINDER: Specification may require revision to correspond to drawing changes.
   - ___ All views not grouped together. Fig(s)_____
   - ___ Views connected by projection lines or lead lines. Fig(s)_____

   Partial views. 37 CFR 1.84(h) 2
   - ___ View and enlarged view not labled separatly or properly. Fig(s)_____

   Sectional views. 37 CFR 1.84 (h) 3
   - ___ Hatching not indicated for sectional portions of an object. Fig(s)_____
   - ___ Cross section not drawn same as view with parts in cross section with regularly spaced parallel oblique strokes. Fig(s)_____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - ___ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s)_____
9. SCALE. 37 CFR 1.84(k)
   - ___ Scale not large enough to show mechanism with crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s)_____
   - ___ Indication such as "actual size" or scale 1/2" not permitted. Fig(s)_____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
    - ___ Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (except for color drawings). Fig(s)_____
11. SHADING. 37 CFR 1.84(m)
    - ___ Solid black shading areas not permitted. Fig(s)_____
    - ___ Shade lines, pale, rough and blurred. Fig(s)_____
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
    - ___ Numbers and reference characters not plain and legible. 37 CFR 1.84(p)(1) Fig(s)_____
    - ___ Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(p)(1) Fig(s)_____
    - ___ English alphabet not used. 37 CFR 1.84(p)(2) Fig(s)_____
    - ___ Numbers, letters, and reference characters do not measure at least .32 cm. (1/8 inch) in height. 37 CFR(p)(3) Fig(s)_____
13. LEAD LINES. 37 CFR 1.84(q)
    - ___ Lead lines cross each other. Fig(s)_____
    - ___ Lead lines missing. Fig(s)_____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
    - ___ Sheets not numbered consecutively, and in Arabic numerals, beginning with number 1. Sheet(s)_____
15. NUMBER OF VIEWS. 37 CFR 1.84(u)
    - ___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s)_____
    - ___ View numbers not preceded by the abbreviation Fig. Fig(s)_____
16. CORRECTIONS. 37 CFR 1.84(w)
    - ___ Corrections not made from prior PTO-948. Fig(s)_____
17. DESIGN DRAWING. 37 CFR 1.152
    - ___ Surface shading shown not appropriate. Fig(s)_____
    - ___ Solid black shading not used for color contrast. Fig(s)_____

COMMENTS:

ATTACHMENT TO PAPER NO. 4 REVIEWER VMS DATE 10/31/96

PTO Copy

WHITE & CASE
1155 Avenue of the Americas
New York, NY 10036-2787

Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Date: April 9, 1998
File No. 1132839-014

Applicant	:	Henning Munk Ejlersen	
Serial No.	:	08/696,898	Examiner: Stright, R.
Filed	:	August 26, 1996	Art Unit: 3306
Title	:	Needle Unit	

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for

April 9, 1998
Date of Deposit

Robert B. Smith — Attorney Name
28,538 — Registration No.

Signature
April 9, 1998
Date of Signature

04/15/1998 SLUONG 00000001 231703 08696898
01 FC:117 950.00 CH

Docket No. 1132839-01-

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

2. ( ) The fee has been calculated as shown below:

Claims remaining		Prior Paid Claims		Extra	Rate		Fee
Total:	minus	(at least 20)	=		@ $22	=	$
Independent	minus	(at least 3)	=		@ $82	=	$____

TOTAL ADDITIONAL FEE: $

3. (X) An extension of time to respond to the PTO Communication dated October 14, 1997 is hereby requested. The required fee, indicated below, is enclosed herewith:

Within first month:	( )	$110
Within second month	( )	$450
Within third month	(X)	$950
Within fourth month	( )	$1,510
Within the fifth month	( )	$2,060

4. ( ) Enclosed please find a check in the amount of $_____ representing (a) additional claims fee ($ 0) and (b) the extension fee ($).

5. (X) The Commissioner is hereby authorized to charge the amount of $950 representing (a) additional claims fee ($ 0) and (b) the extension fee ($950) to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

Docket No. 1132839-01

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 23-1703. A copy of this sheet is enclosed.

WHITE & CASE

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 819-8547
smithro@newyork.whitecase.com

Docket No: 1132839-0145-4-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#6/B w/Ret

Applicant	:	Henning Munk Ejlersen	
Serial No.	:	08/696,898	Examiner: Stright, R.
Filed	:	August 26, 1996	Art Unit: 3306
Title	:	Needle Unit	

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on April 9, 1998.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — Signature

April 9, 1998 — Date

April 9, 1998

AMENDMENT

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

In response to the Office Action dated October 9, 1997, please amend the above-identified application as follows:

ABSTRACT:

Please add the Abstract which is attached hereto.

IN THE DRAWINGS:

Enclosed please find copies of Figs. 1 and 10 with proposed revisions in red.

IN THE SPECIFICATION:

On page 1, between lines 1 and 2 (i.e., after "NEEDLE UNIT" and before "The invention relates..."), insert:

- - BACKGROUND OF THE INVENTION

Field of Invention - -

On page 1, after line 7 and before line 8, insert:

- - Description of Related Art - -

On page 1, after line 23 and before line 24, insert:

- - SUMMARY OF THE INVENTION - -

On page 4, after line 17 and before line 18, insert:

- - BRIEF DESCRIPTION OF THE DRAWINGS - -

On page 5, after line 27 and before line 28, insert:

- - DESCRIPTION OF THE PREFERRED EMBODIMENTS - -

On Page 9, lines 6-7, replace "(not shown)" with – 19 –.

IN THE CLAIMS:

Cancel claims 8-9 and substitute the following claims therefor:

--10. In combination a magazine and a removable needle unit,

wherein said needle unit comprises a needle mounted in a hub and a sleeve made from a deformable material surrounding an end of the needle at a distance from said needle, said sleeve being designed to be snap-locked onto the outlet end of a syringe in a manner such that the locking engagement between said sleeve and the syringe outlet end is released when specific zones of said sleeve are pressed radially inwardly; and

wherein said magazine comprises a compartment for accommodating said needle unit in a plurality of rotational positions; and wherein said needle unit and magazine further include a syringe/needle unit release mechanism which does not press said zones radially inwardly in a first rotational position of said needle unit, such that the needle unit may lock onto a syringe outlet end, and which presses said zones radially inwardly in a second rotational position of said needle unit, thereby causing said needle unit to release from a syringe outlet end.

11. A magazine and needle unit according to claim 10, wherein said syringe/needle unit release mechanism comprises protrusions provided on the needle hub at said zones and a reinforcement part in said magazine which engages said protrusions in said second rotational position to press said zones inwardly, and which includes recesses to receive said protrusions in said first rotational position so as not to press said zones inwardly.

12. A magazine and needle unit according to claim 10, wherein said syringe/needle unit release mechanism comprises a plurality of axial ribs on an inner wall of said magazine which press said specific zones inwardly in said second rotational position, and wherein said sleeve

includes a plurality of axial recesses for receiving said ribs in said first rotational position so as not to press said zones inwardly.

~~13~~ 12. A magazine and needle unit according to claim ~~10~~ 1, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

~~14~~ 13. A magazine and needle unit according to claim ~~13~~ 12, wherein said flange and said compartment are one integral plastic member.

15. A magazine and needle unit according to claim ~~13~~ 12, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

~~16~~ 14. A magazine and needle unit according to claim ~~14~~ 13, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

~~17~~ 2. A magazine and needle unit according to claim ~~11~~ 1, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

~~18~~ 3. A magazine and needle unit according to claim ~~17~~ 2, wherein said flange and said compartment are one integral plastic member.

~~19~~ 4. A magazine and needle unit according to claim ~~17~~ 3, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

~~20~~ 5. A magazine and needle unit according to claim ~~18~~ 4, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

8 7
~~21~~. A magazine and needle unit according to claim ~~12~~, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

9 8
~~22~~. A magazine and needle unit according to claim ~~21~~, wherein said flange and said compartment are one integral plastic member.

11 8
~~23~~. A magazine and needle unit according to claim ~~21~~, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

10 9
~~24~~. A magazine and needle unit according to claim ~~22~~, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment. - -

REMARKS

The proposed revision to Fig. 1 of the drawings illustrates a foil seal as described on page 9, line 6-7 of the original specification ("a foil sealed along the flange 17"), in order to overcome the objection to the drawings set out in paragraph 2 of the last Office Action. It is respectfully submitted that the proposed revision to Fig. 1 merely shows what is described in the specification and therefore does not constitute new matter. Approval of the proposed drawing correction is thus respectfully requested.

The specification has been amended, at page 9, lines 6-7, to refer to the foil seal of Fig. 1 as element "19".

In Fig. 10, the proposed corrections would add lead lines to elements 3, 8, and 10, in order to overcome the objection set out in paragraph 3 of the last Office Action. The Examiner also noted that the numeral "13" lacked a lead line. However, Fig. 10 contained the numeral "13" twice and, rather than being redundant, the second occurrence of the numeral "13" in Fig. 10 has been eliminated. Approval of these drawing corrections is sought as well.

With regard to paragraphs 4-5 of the Office Action, an Abstract is submitted herewith, and the application has been amended to add appropriate section headings (the applicant notes that the "claims" section is already denoted as such). The Abstract substantially conforms to the Abstract of the published PCT application, except that the needle sleeve is referred to for clarity as being a "deformable" material rather than a "flexible" material, to clarify that such material need not be elastomeric. As disclosed in the instant specification (e.g., page 1, lines 4-5), such sleeves are more typically made of plastic.

In paragraph 6 of the last Office Action, claims 5-9 were rejected under 35 U.S.C. § 112, paragraph 2, because it was unclear whether such claims were directed to a combination or merely to a magazine, and whether such claim was meant to be in "Jepson" format. Claims 5-9 have been canceled, and new claims 10-24 are submitted herewith, which are directed to the combination of a magazine and removable needle unit. The new claims are not in "Jepson" format.

Claims 5-9 were rejected as being unpatentable over Poncy U.S. patent No. 4,961,730 either alone or in combination with Meierhoefer U.S. patent No. 3,989,044. New claims 10 - 24 have been written to point out, with greater particularity, the novel features of the present invention.

The present invention is directed to a needle unit which is stored in a magazine until use. Prior to use, the needle unit is disposed in the magazine at a first rotational position so that, when the needle hub is mounted on the forward end of a cooperating syringe, it locks onto the syringe, allowing the magazine to be removed, thereby exposing the needle. The needle unit sleeve contains certain zones which, when pressed inwardly, cause the needle unit to release from a syringe. After the needle is used, the needle unit is re-inserted into the magazine so as to be oriented at a second rotational position. The needle unit and magazine include a syringe/needle unit release mechanism which, in this second rotational position, presses the release zones inwardly, causing the used needle unit to disengage from the syringe. In this manner, the used needle will remain with the magazine for disposal. Moreover, in this second rotational position, used needles will not snap onto a syringe again, thus preventing inadvertent (or deliberate) reuse.

New claim 10 has been drafted to the combination of a magazine and needle unit which have the foregoing features.

New dependent claim 11 recites that the syringe/needle unit release mechanism comprises protrusions on the needle hub, for example, the protrusions 8 shown in Fig. 1, and a reinforcement part, such as a reinforcement ring 13, which, when engaged with one another, press the sleeve inwardly to release the needle unit from a syringe.

New dependent claim 12 recites that the syringe/needle unit release mechanism comprises axial ribs on the magazine's inner wall, such as ribs 15 of Fig. 8, which are receive in a plurality of axial recesses 14 in the sleeve when it is desired to have the needle unit lock onto a syringe (first rotational position), but which in a second rotational position press the sleeve inwardly when it is desired to cause the needle unit to release from a syringe.

The remaining dependent claims recite additional desirable features of the invention.

The device disclosed in Poncy has a needle coupling which is not of the snap-on type, and thus it has no locking element which can be released by pressing specific zones of the needle unit. Also, the Poncy needle is not stored in a magazine which, in a first rotational position, will allow the needle unit to snap onto a syringe but which, in a second rotational position, will cause the needle unit to release from the syringe. Instead of such a magazine, Poncy is provided with a sheath which can be removed to expose the needle and reapplied to cover the needle. However, when the sheath is reapplied, no release of the connection between the syringe and needle results, and nothing prevents such needle from being re-used on the same or another syringe.

For such reasons, favorable consideration and allowance of claims 10-24 are respectfully requested.

In connection with former claims 8-9, the Examiner cited the Meierhoefer patent as disclosing the use of a foil seal. New dependent claims 15-16, 19-20, and 23-24 recite a removable foil over the open end of the magazine. The applicant does not dispute that the use of a foil seal *per se* is novel. However, favorable consideration and allowance of these claims is respectfully requested for the reasons recited above in connection with the remaining claims, and based on the additional advantages that the claimed foil seal provides when used with the structure recited in the parent claims.

For the reasons, discussed above, favorable consideration and allowance of the application are respectfully requested.

Respectfully submitted,

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 819-8547

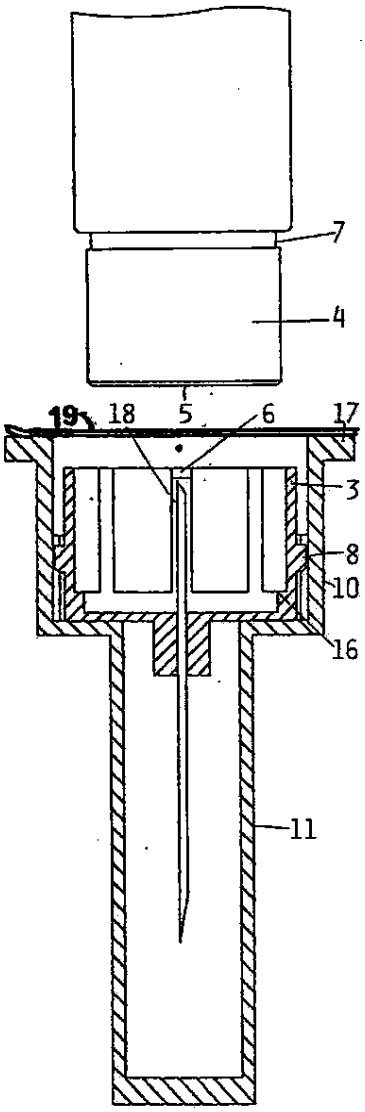

Fig. 1

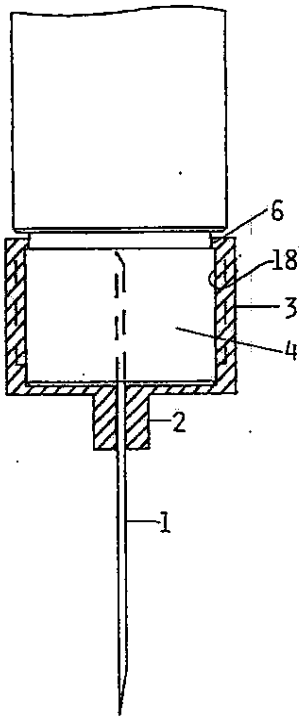

Fig. 2

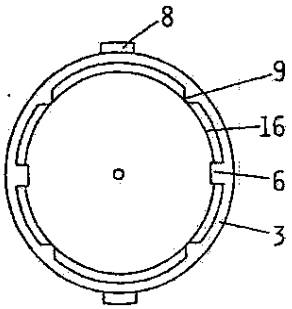

Fig. 3

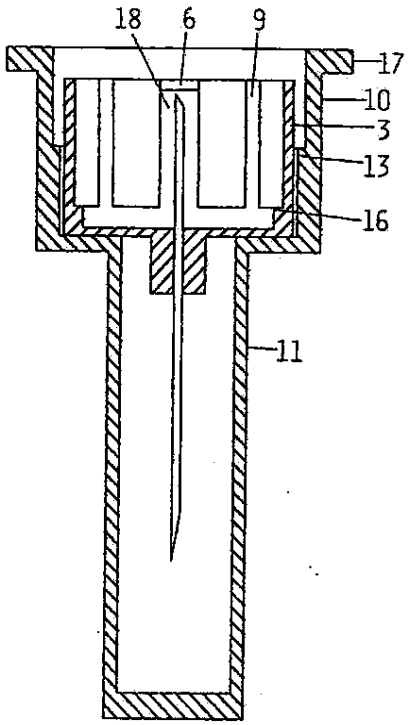

Fig. 7

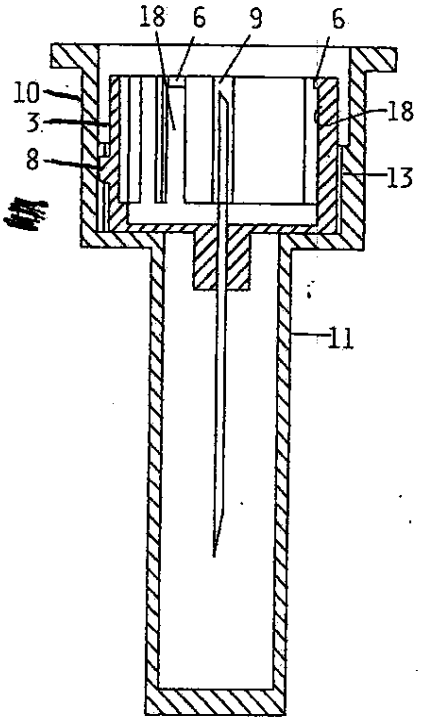

Fig. 10

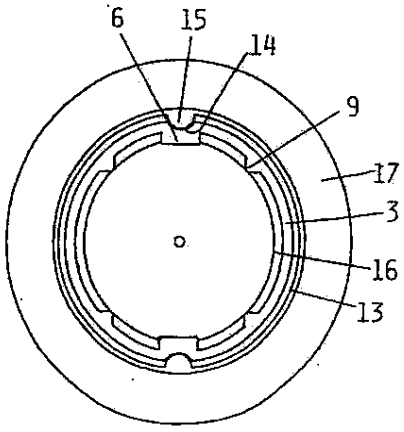

Fig. 8

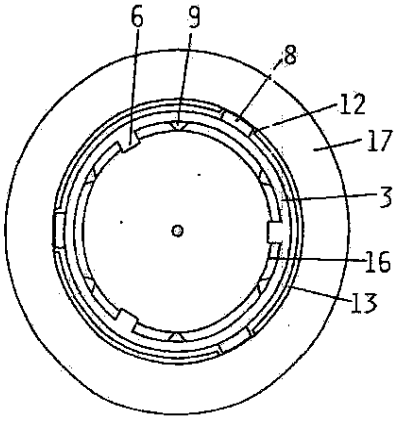

Fig. 11

approved 7/7/98 JG

Docket No: 1132839-914

08/696,898

ABSTRACT

A needle unit comprises a needle mounted in a hub having a sleeve made from a deformable material and surrounding an end of the needle at a radial distance from that needle. The sleeve is designed to be snap-locked onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging a circumferential recess in the outer wall of the connecting piece. It is also designed such that the locking engagement between the protrusions of this sleeve and the recess of the connecting piece is released when certain zones of the outer sleeve wall are pressed inwardly. A magazine for storing the needle unit comprises a compartment which can receive the needle unit in a plurality of rotational positions. The needle unit and magazine include a syringe/needle unit release mechanism which, in a first rotational position, does not press the release zones inwardly, thereby allowing the needle unit to lock onto the syringe, but which in a second rotational position, presses the release zones inwardly so that the needle disengages from the syringe and remains inside the magazine for disposal.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/668,298	06/22/96	EJLERSEN	H 3997.204-US

QM31/0727

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

EXAMINER	
STRIGHT,R	
ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 07/27/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

PTOL-90 (Rev. 6/84)

2 - APPLICANT'S COPY

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	7

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4/13/98 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 16-24 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 5-9 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 10-24 are rejected.
5. ■ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☒ The proposed additional or substitute sheet(s) of drawings, filed on 4/13/98. has (have) been ☒ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

DETAILED ACTION

Drawings

1. The corrected or substitute drawings were received on April 13, 1998. These drawings are approved by the examiner.

2. The drawings are objected to because in figure 4, numeral 3 to the sleeve needs to reference the needle hub and not the magazine. Correction is required.

Claim Rejections - 35 USC § 112

3. Claims 10-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite because it is unclear how the sleeve is "designed to be snap-locked" onto the end of a syringe. This language fails to positively establish any structure and only inferentially references that structure located within this functional recitation, i.e. the specific zones, etc. Applicant appears to intend to positively recite the zones of the sleeve. The zones lack antecedent basis since they have only been inferentially referenced in the function of the sleeve design. It is further unclear where these "zones" are located on the sleeve. It is unclear what "syringe/needle unit release mechanism" is to encompass structurally. The structure is claimed as singular, however, is claimed as being on two separate elements.

In claims 11 and 12, "said zones" lack antecedent basis. Claim 11 is further unclear where the protrusions are provided since the locations of the zones on the sleeve have never been established.

Allowable Subject Matter

4. Claims 10-24 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

5. Applicant's arguments filed April 13, 1998 have been fully considered and are considered persuasive. The prior art made of record fails to disclose the combination of elements including the syringe/needle release mechanism which is structure on the magazine and the needle unit that interacts with each other to allow the sleeve to be pressed and releases from the syringe in one rotational position to lock the needle within the magazine and allows the syringe to connect to the sleeve in another rotational position to allow the needle to be used.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note the prior art shows different forms of needle magazines utilizing caps or seals at

the ends thereof for protection and for keeping the devices sterile as well as other claimed elements of the needle unit and magazine combination.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Stright whose telephone number is (703) 308-2113. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood Coggins, can be reached on (703) 308-1344. The Official Fax phone number for this Group is (703) 305-3590. All formal faxes must go to this number. The art unit fax phone number is (703) 306-4520. All informal faxes may be sent to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Please note that the art unit number has changed from Art Unit 3306 to Art Unit 3734 and the Group number has changed from Group 3300 to Sector 3700 on April 1, 1998.

rs
July 7, 1998

RONALD STRIGHT
PRIMARY EXAMINER

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP–APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
NOTICE OF REFERENCES CITED	08/696,898	3734	7
	APPLICANT(S) EJLERSEN		

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	4840272	6/20/89	Goldman	206	365	
	B	4968304	11/6/90	Alter et al	604	263	
	C						
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L	1008136	5/52	France	Lévy-Cavallerie et al	206	365		
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R	
S	
T	
U	

EXAMINER	DATE
[signature]	7/7/98

*A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

GAU - 3734

Notice of Appeal
PATENT
Docket No. 3997.204-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Henning Munk Ejlersen	
Serial No.	:	08/696,898	Examiner: Stright, R.
Filed	:	August 22, 1996	Art Unit: 3734
Title	:	Needle Unit	

January 27, 1999

NOTICE OF APPEAL FROM PRIMARY EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

noted
RS
2/9/99

Assistant Commissioner For Patents
Washington, D.C. 20231

Sir:

The applicant(s) hereby appeal(s) to the Board of Patent Appeals and Interferences from the decision dated July 27, 1998, of the Primary Examiner finally rejecting claims 10-24.

The items checked below are appropriate:

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, DC 20231 on January 27, 1999.

Robert B. Smith Reg. No. 28,538

Robert B. Smith January 27, 1999
Signature Date

02/02/1999 SLUANG1 00000105 231703 08696898

01 FC:117 870.00 OP
02 FC:119 300.00 CH

Docket No. 3997.204-US

1. **STATUS OF APPLICANT**

This application is on behalf of a large entity.

2. **FEE FOR FILING NOTICE OF APPEAL**

Pursuant to 37 C.F.R. 1.17(e) the fee for filing the Notice of Appeal is

( ) small entity $150.00

(X) other than a small entity $300.00

Notice of Appeal Fee due $ 300.00

3. **EXTENSION OF TIME**

(a) (X) Extension requested (check below the total number of months of extension requested):

Extension (months)	Fee for other than small entity	Fee for small entity
( ) one month	$110.00	$ 55.00
( ) two months	380.00	190.00
(X) three months	870.00	435.00
( ) four months	1,360.00	680.00

Extension Fee Due: $870.00

(check and complete the next item, if applicable)

( ) An extension for months has already been secured. The net extension fee due is $.

(X) In the event that an extension of time is required, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee extension of time.

4. **TOTAL FEE DUE**

The total fee due is

Notice of Appeal fee $ 300.00
Extension fee (if any) $ 870.00

TOTAL FEE DUE $ 1,170.00

5. FEE PAYMENT

(X) Attached is a check in the sum of $ 870.00 for the extension fee.

(X) Charge Deposit Account No. 23-1703 the sum of $ 300.00 for the appeal fee. A copy of this sheet is enclosed provided for such purpose.

6. FEE DEFICIENCY

(X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this communication to Deposit Account No. 23-1703. A copy of this sheet is provided for such purpose.

Respectfully submitted,

Robert B. Smith

Robert B. Smith
Reg. No. 28,538

White & Case
1155 Avenue of the Americas
New York, New York 10036

Attorney for Applicant(s)
(212) 819-8547

AF/EOM 3734
EE
5:9-99
#9
Ent 1

WHITE & CASE
1155 Avenue of the Americas
New York, NY 10036-2787

Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Date: April 21, 1999
File No. 3997.204-US

Applicant	:	Henning Munk Ejlersen		
Serial No.	:	08/696,898	Examiner: Stright, R.	
Filed	:	August 22, 1996	Art Unit: 3734	
Title	:	Needle Unit		

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on

April 21, 1999.
Date of Deposit

Robert B. Smith — 28,538
Attorney Name — Registration No.

Robert B. Smith — April 21, 1999
Signature — Date of Signature

04/28/1999 MBLANCO 00000075 231703 08696898
01 FC:115 110.00 CH

Docket No. 3997.204-US

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

2. ( ) The fee has been calculated as shown below:

Claims remaining		Prior Paid Claims		Extra		Rate		Fee
Total:	minus	(at least 20)	=		@	$22	=	$
Independent	minus	(at least 3)	=		@	$82	=	$

TOTAL ADDITIONAL FEE: $

3. (X) A one month extension of time to file the appeal brief is hereby requested. The required fee is indicated below:

Within first month:	(X)	$110
Within second month	( )	$380
Within third month	( )	$870
Within fourth month	( )	$1,360
Within the fifth month	( )	$1,850

4. ( ) Enclosed please find a check in the amount of $ 0.00 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 110 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 110) to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

Docket No. 3997.204-US

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 23-1703. A copy of this sheet is enclosed.

WHITE & CASE

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 819-8547
smithro@newyork.whitecase.com

Docket No: 3997.204-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Henning Munk Ejlersen	
Serial No.	:	08/696,898	Examiner: Stright, R.
Filed	:	August 22, 1996	Art Unit: 3734
Title	:	Needle Unit	

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on April 21, 1999.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — April 21, 1999
Signature — Date

April 21, 1999

AMENDMENT AFTER FINAL REJECTION

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicant respectfully requests that the following amendment be entered in order to place the application in allowable form:

IN THE DRAWINGS:

Enclosed please find a copy of the drawing sheet containing Fig. 4 with a proposed revision in red.

IN THE CLAIMS:

Rewrite claims 10-12 as follows:

--10. (Amended) In combination a magazine and a removable needle unit, wherein said needle unit comprises a needle mounted in a hub and a sleeve made from a deformable material surrounding an end of the needle at a distance from said needle, said sleeve including at least one snap-lock element [being] designed to engage a cooperating element on [be snap-locked onto] the outlet end of a syringe for securing said needle unit on the syringe, and wherein said sleeve includes specific zones, spaced from said at least one snap-lock member, which when pressed radially inwardly deform said sleeve in a manner such that the locking engagement between said sleeve and the syringe outlet end is released [when specific zones of said sleeve are pressed radially inwardly]; and

wherein said magazine comprises a compartment for accommodating said needle unit in a plurality of rotational positions; and wherein said needle unit and magazine further include a syringe/needle unit release [mechanism] means which does not press said zones radially inwardly in a first rotational position of said needle unit, such that the needle unit may lock onto a syringe outlet end, and which presses said zones radially inwardly in a second rotational position of said needle unit, thereby causing said needle unit to release from a syringe outlet end. --

--11. (Amended) A magazine and needle unit according to claim 10, wherein said syringe/needle unit release [mechanism] means comprises protrusions provided on the needle hub at said zones and a reinforcement part in said magazine which engages said protrusions in said second rotational position to press said zones inwardly, and which includes recesses to receive said protrusions in said first rotational position so as not to press said zones inwardly. --

Docket No. 3997.204-US

--12. A magazine and needle unit according to claim ~~10~~, wherein said syringe/needle unit release [mechanism] means comprises a plurality of axial ribs on an inner wall of said magazine which press said specific zones inwardly in said second rotational position, and wherein said sleeve includes a plurality of axial recesses for receiving said ribs in said first rotational position so as not to press said zones inwardly. --

REMARKS

The applicant thanks the Examiner for the indication that claims 10-24 recite patentable subject matter. The foregoing proposed amendment is directed to overcoming the remaining formal rejections to the claims. Also, the proposed drawing revision is responsive to the Examiner's objection that the numeral "3" in Figure 4 should point to the needle hub and not the magazine.

In the last Office Action, claim 10 was rejected under 35 U.S.C. § 112, second paragraph, because it did not specify how the sleeve is designed to be snap-locked onto the end of a syringe, and because the "specific zones" were not positively recited. The foregoing amendment would specify that the sleeve has at least one snap-lock element, such as protrusions 6 (but alternatively some other element, such as a recess), which is designed to engage a cooperating element on a syringe outlet end, such as a recess 7, so that the needle unit and syringe snap-lock together when the needle sleeve is in its undeformed state (i.e., when the specific zones are not compressed). Claim 10 would further recite the "specific zones" as a positive claim element, being part of the sleeve, which when pressed radially inwardly deform the sleeve so as to release the

snap-lock element. The applicant believes that claim 10, as thus amended, would specify how the sleeve snap-locks onto, and is released from, a syringe, and would overcome the rejection based on inferential claiming.

Claim 10 was also rejected because the term "syringe/needle unit mechanism" was unclear. By the foregoing amendment, such term would be changed to "syringe/needle unit means", specific examples of such means being recited in claims 11 and 12.

With the foregoing amendments, the term "said zones" in claims 11 and 12 would have proper antecedent basis and, because the location of the zones is now specified in claim 10, the location of the protrusions in claim 11 would be clear.

In light of the fact that the foregoing amendments are presented merely to overcome the formal rejections under §112, entry of the amendments, and allowance of the application, are respectfully requested.

Respectfully submitted,

Robert B. Smith

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 819-8547

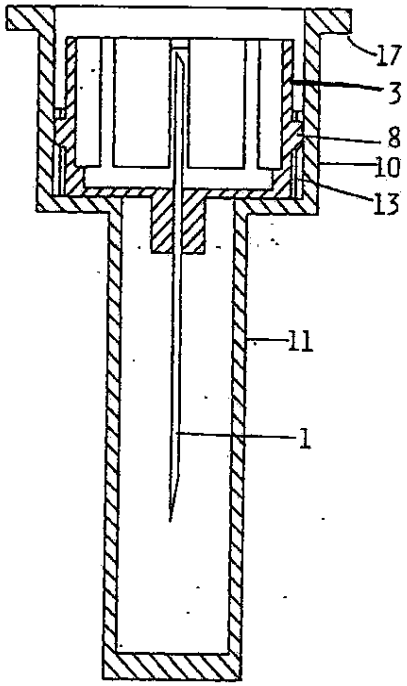

Fig. 4

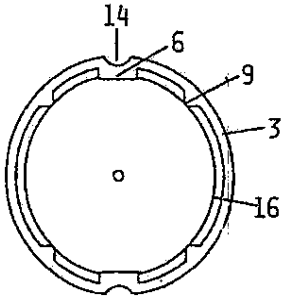

Fig. 6

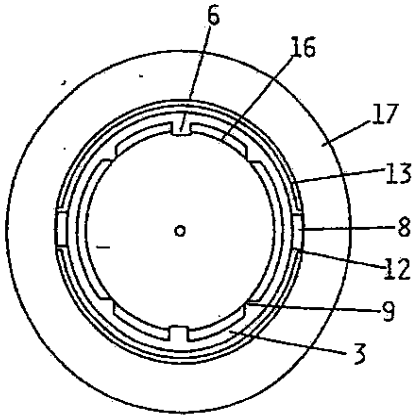

Fig. 5

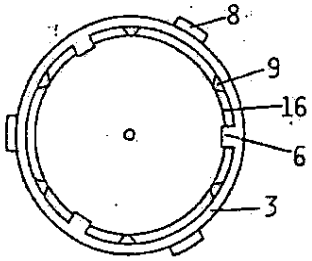

Fig. 9

OK pgs 4/9/99

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/696,898	08/22/96	EJLERSEN	H 3997.204-US

EXAMINER	
STRIGHT, R	
ART UNIT	PAPER NUMBER
3762	11

DATE MAILED: 06/18/99

0M31/0618

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

NOTICE OF ALLOWABILITY

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to the Amendment of 4/26/99.

☒ The allowed claim(s) is/are 10-24.

☐ The drawings filed on _____ are acceptable.

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. ____.

☒ including changes required by the proposed drawing correction filed on 4/13/98 & 4/26/99, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☐ Examiner's Statement of Reasons for Allowance

RONALD K. STRIGHT, JR
PRIMARY EXAMINER

PTOL-37 (Rev. 10/95)

*U.S. GPO: 1997-417-381/62707

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
[illegible]56,898	[illegible]2/96		STRI[illegible] [illegible]	[illegible]

First Named Applicant: EJLERSEN, 35 USC 154(b) term ext. = 0 Days.

TITLE OF INVENTION: NEEDLE UNIT

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
[illegible]7.204	[illegible]4-2	[illegible]	UTILITY	NO	[illegible]	[illegible]

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or

B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

PTOL-85 (REV. 10-96) Approved for use through 06/30/99. (0651-0033)

OIPE JCS [stamp] SEP 1 0 1999 PATENT & TRADEMARK OFFICE

PART B—ISSUE FEE TRANSMITTAL

#B

Complete and mail this form, together with applicable fees, to: **Box ISSUE FEE**
Assistant Commissioner for Patents
Washington, D.C. 20231

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1) 0618

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10017

Note: The certificate of mailing below can only be used for domestic mailings of the Issue Fee Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Certificate of Mailing

I hereby certify that this Issue Fee Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

Gina Maldonado (Depositor's name)

[signature] (Signature)

Sept. 1, 1999 (Date)

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/	96		STRIGHT 3762	/99

First Named Applicant: EJLERSEN, 35 USC 154(b) term ext. = 0 Days.

TITLE OF INVENTION: NEEDLE UNIT

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
204			UTILITY	NO		/95

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.
   - ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
   - ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
   1 Steve T. Zelson, Es
   2 ____
   3 ____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)
PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.
(A) NAME OF ASSIGNEE Novo Nordisk A/S
(B) RESIDENCE: (CITY & STATE OR COUNTRY) Novo Alle, DK-2880 Bagsvaerd, Denmark
Please check the appropriate assignee category indicated below (will not be printed on the patent)
☐ individual ☒ corporation or other private group entity ■ government

4a. The following fees are enclosed (make check payable to Commissioner of Patents and Trademarks):
☐ Issue Fee
☐ Advance Order - # of Copies ____

4b. The following fees or deficiency in these fees should be charged to:
DEPOSIT ACCOUNT NUMBER 14-1447
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The COMMISSIONER OF PATENTS AND TRADEMARKS IS requested to apply the Issue Fee to the application identified above.

(Authorized Signature) [signature] (Date) 9/1/99

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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SAN00827969

Attorney Docket No.: 3997.204-US

PATENT

Issue Batch Number: U61

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: 08/696,898 Group Art Unit: 3762

Filed: August 22, 1996 Examiner: Stright, R.

For: Needle Unit

SUBMISSION OF FORMAL DRAWINGS

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Applicants submit herewith 5 sheets of formal drawings, containing Figures 1-17 for the above-captioned application. The formal drawings are being filed in response to the request contained in the Attachment to the Notice of Allowance and Issue Fee Due, mailed **June 10, 1999**, and should be substituted for the corresponding sheets of informal drawings of the originally filed application.

Respectfully submitted,

Date: August 6, 1999

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

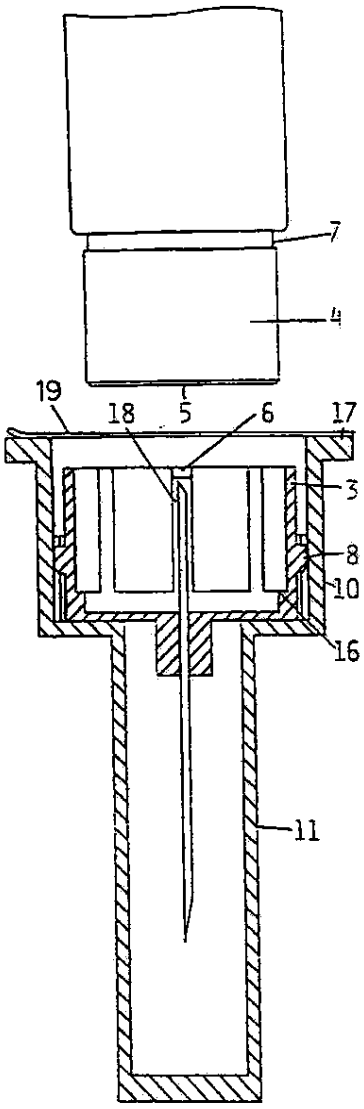


Fig. 1

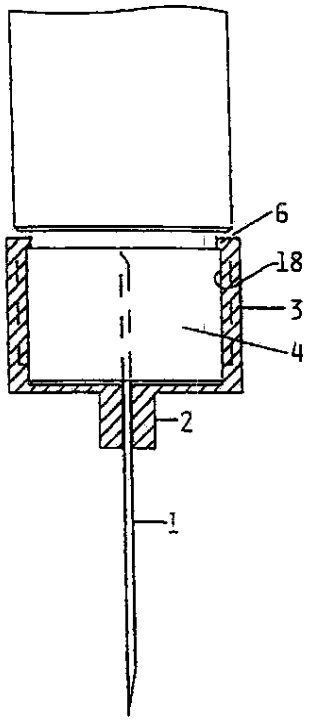


Fig. 2

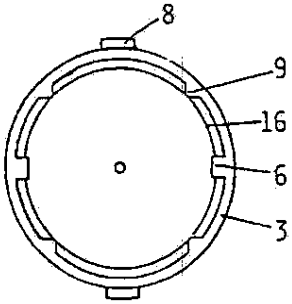


Fig. 3

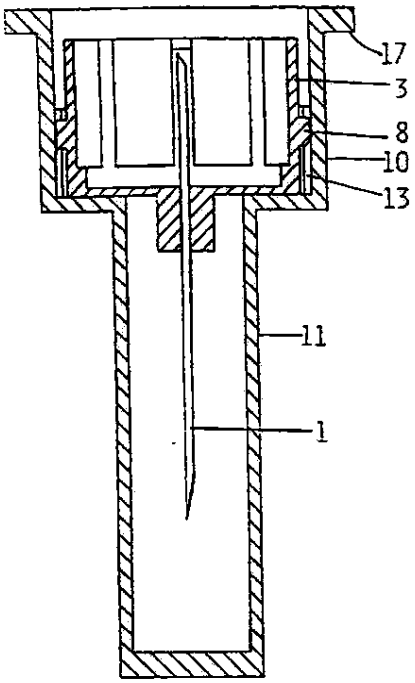


Fig. 4

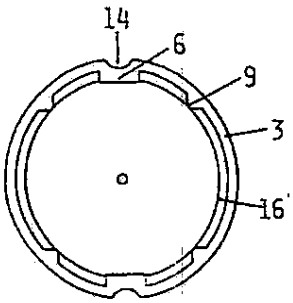


Fig. 6

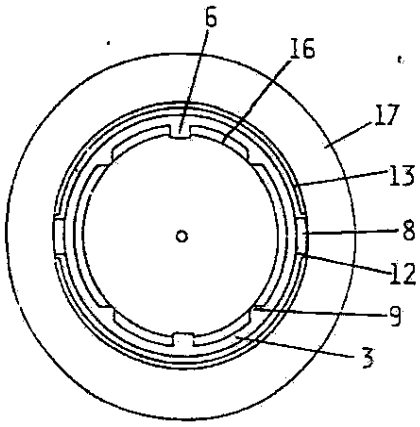


Fig. 5

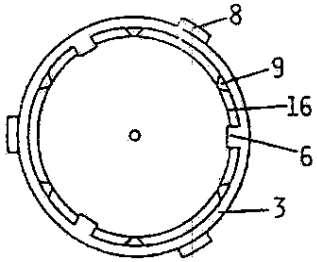


Fig. 9

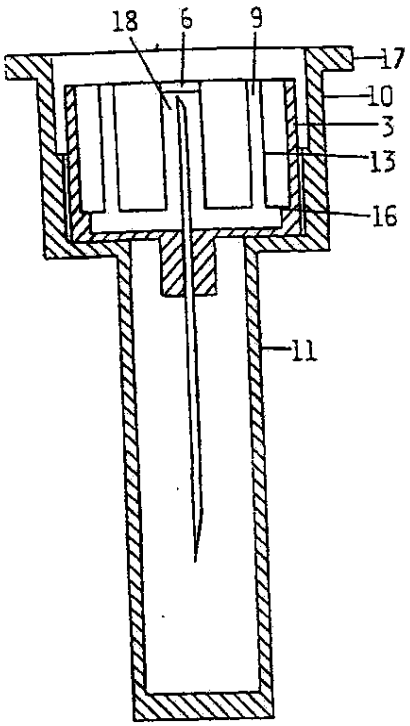


Fig. 7

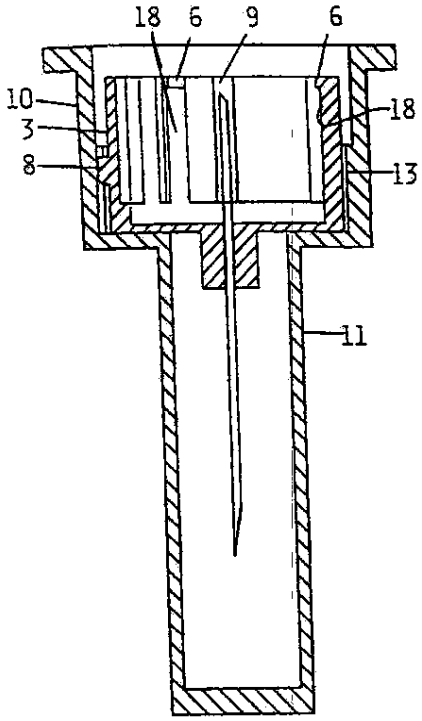
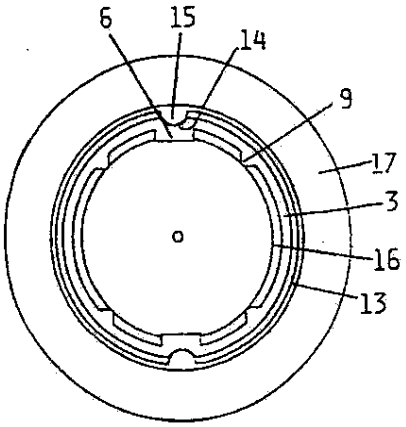


Fig. 10



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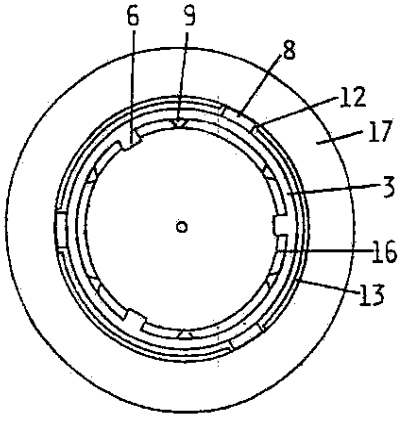

Fig. 11

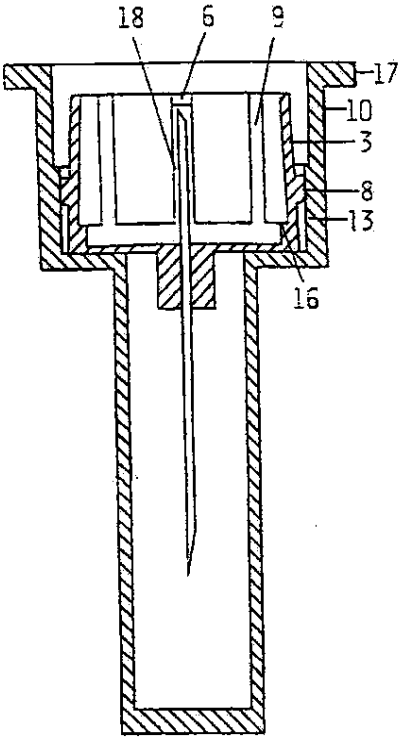

Fig. 12

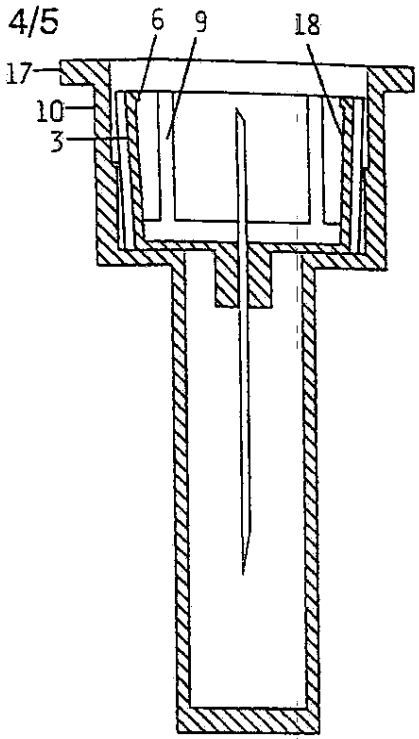

Fig. 14

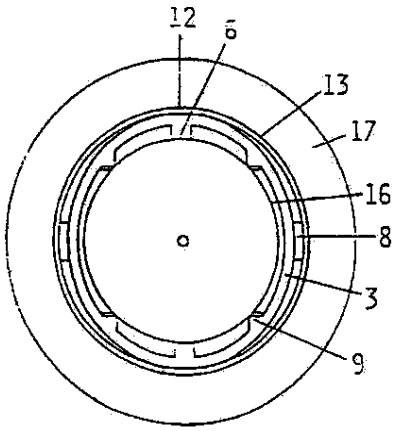

Fig. 13

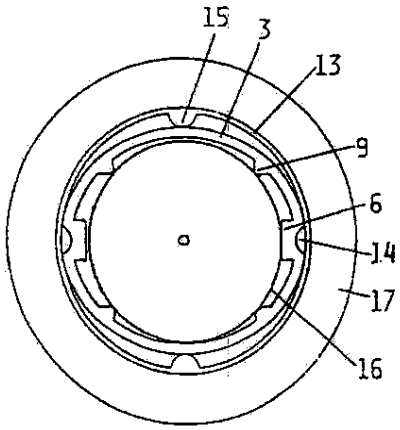

Fig. 15

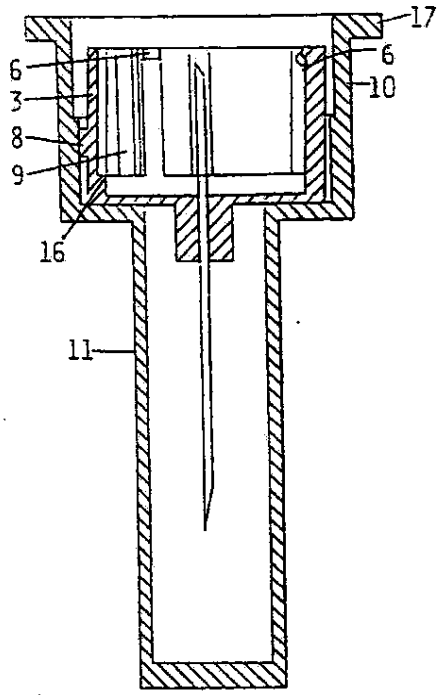

Fig. 16

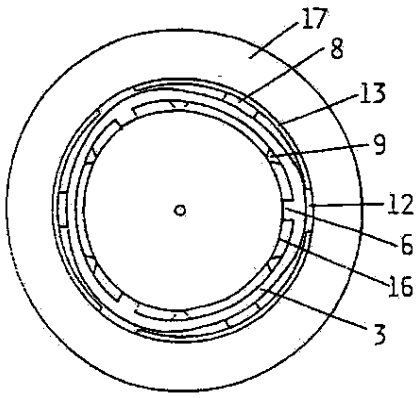

Fig. 17

Attorney Docket No.: 3997.204-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henning Munk Ejlersen

Serial No.: 08/696,898 Group Art Unit: 3762

Filed: August 22, 1996 Examiner: Stright, R.

For: Needle Unit

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Submission of Formal Drawings
2. 5 Sheets of Formal Drawings

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Attn: Official Draftsman
Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

on August 6, 1999

Gina Maldonado
(name of person mailing paper)

(signature of person mailing paper)